

EXHIBIT K



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,890	01/23/2006	6066168	067448-0000004	5461
24201	7590	12/21/2006	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			ART UNIT	PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.



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MCLEAN, VA 22102

***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/007,890.

PATENT NO. 6066168.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/007,890	Patent Under Reexamination 6066168	
	Examiner Sara S. Clarke	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a ☐ Responsive to the communication(s) filed on _____. b ☐ This action is made FINAL.

c ☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892. 3. ☐ Interview Summary, PTO-474.

2. ☒ Information Disclosure Statement, PTO/SB/08. 4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims 1-18 are subject to reexamination.

1b. ☐ Claims _____ are not subject to reexamination.

2. ☐ Claims _____ have been canceled in the present reexamination proceeding.

3. ☒ Claims 8-10 and 17 are patentable and/or confirmed.

4. ☒ Claims 1-7, 11-16 and 18 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ The drawings, filed on _____ are acceptable.

7. ☐ The proposed drawing correction, filed on _____ has been (7a) ☐ approved (7b) ☐ disapproved.

8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have

1 ☐ been received.

2 ☐ not been received.

3 ☐ been filed in Application No. _____.

4 ☐ been filed in reexamination Control No. _____.

5 ☐ been received by the International Bureau in PCT application No. _____.

* See the attached detailed Office action for a list of the certified copies not received.

9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

10. ☐ Other: _____

cc: Requester (if third party requester)

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DETAILED ACTION

Statutory Bases for Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 1-7 and 12-16** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,104,404 to Wolff ("Wolff").
2. Regarding claim 1, Wolff discloses the invention as claimed including a longitudinally flexible stent. Fig. 2 of Wolff shows the stent in a longitudinally flexed position. As shown in Fig. 1, Wolff further discloses a plurality of cylindrical rings 12, which are connected so as to be generally aligned on a common longitudinal axis. As disclosed at col. 1, l. 55, the segments used in Wolff can be those disclosed in US

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Patent No. 4,830,003 (also to Wolff). As disclosed in Wolff '003, at col. 3, ll. 12-14, the stent segments disclosed in Wolff '003 are expandable in the radial direction. As disclosed at the abstract, l. 2, Wolff discloses at least one weld connection between each cylindrical ring to attach the plurality of cylindrical rings along the common longitudinal axis thereby forming the longitudinally flexible stent.

3. Regarding claims 2-5, see Fig. 1.
4. Regarding claim 7, see Figs. 1-5.
5. Regarding claim 12, the rings 12 shown in Fig. 1 have an undulating pattern of peaks and valleys. Moreover, adjacent rings are out of phase with one another. As disclosed at the abstract, l. 2, Wolff discloses at least one weld connection between each cylindrical ring to attach the plurality of cylindrical rings along the common longitudinal axis thereby forming the longitudinally flexible stent.

Regarding claim 6 and 12, Fig. 11 of the subject patent is the only figure for which the rings/elements are described as and appear to be out of phase. Since the peaks of every ring are also the valleys, depending upon perspective, the pairs of portions of adjacent rings, which are connected by interconnecting elements 13, can be called "peaks." In this same manner, the peaks of one cylindrical ring of Wolff point towards the peaks of an adjacent ring.

6. Regarding claim 13, see Fig. 8.
7. Regarding claims 14 and 15, see Fig. 1.
8. Regarding claim 16, the language "one of N-1 adjacent weld connections" is not exclusive. Since Wolff discloses two weld connections between adjacent rings, Wolff necessarily discloses one weld connection between adjacent rings.

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9. **Claims 11 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,344,053 to Boneau ("Boneau") in view of Wolff.

10. Boneau discloses the invention substantially as claimed including a plurality of cylindrical rings (see col. 6, ll. 6-19) each having a diameter and a length. Claims 11 and 18 further require that each of the cylindrical rings in an unexpanded and uncrimped condition has a length less than the diameter thereof. At col. 5, ll. 4-22, Boneau discloses that the typical vessel, into which the stent of Boneau might be implanted ranges from 1.5 mm to 5 mm in diameter. Thus, since the cylindrical ring of Boneau is expanded to the vessel diameter (see Fig. 4), the diameter of the cylindrical ring of Boneau, in the expanded position, ranges from 1.5 mm to 5 mm. Boneau further discloses that the stent may have between two and ten turns. See col. 6, line 19. At col. 4, lines 58-60, Boneau discloses a wire diameter in the range of 0.002 to 0.025 inches. Based upon the ranges of the turns and the wire diameter, the diameter of the ring in a crimped position can range from 0.064 to 4.044 millimeters. Boneau also discloses that corresponding stents may range from 1 mm to 2 cm in length. The range of lengths taught by Boneau overlaps a range of lengths less than both the largest crimped diameter of 4.044 mm and the largest expanded diameter of 5 mm. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to make the stent of Boneau with the radially expandable cylindrical rings in an unexpanded and uncrimped condition with a length less than the diameter thereof. See MPEP 2144.05.

11. Boneau does not disclose that the plurality of cylindrical rings are connected so as to be generally aligned on a common longitudinal axis and at least one weld

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connection between each cylindrical ring to attach the plurality of rings along the common longitudinal axis thereby forming the longitudinally flexible stent.

12. As discussed at items 2 and 5 above, Wolff discloses a plurality of cylindrical rings 12, which are connected so as to be generally aligned on a common longitudinal axis and at least one weld connection between each cylindrical ring to attach the plurality of rings along the common longitudinal axis thereby forming the longitudinally flexible stent. As discussed in the abstract, l. 14-18, the welded connections (hinges 14) provide articulation and spacing between the stent segments.

13. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the device of Boneau with the welded hinges taught by Wolff for the purpose of providing articulation and spacing between cylindrical rings.

14. **Claim 1-7 and 12-16** are rejected under 35 U.S.C. 102(b) as being anticipated by the Furui article "Hepatic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents" ("Furui").

15. Regarding claims 1 and 12, Furui discloses a longitudinally flexible stent as shown in Fig. 2c. Fig. 2c shows multiple stents in tandem conforming to the curve of a curved vessel. As shown in Fig. 1, Furui discloses a plurality of cylindrical rings, which are connected by struts so as to be generally aligned on a common longitudinal axis. Finally, Furui discloses the cylindrically shaped elements being expandable in the radial direction. See p. 1, col. 2, l. 28, which discloses the use of *expandable* Gianturco stents.

Claim 1 further requires that there is, "at least one weld connection between each cylindrical ring to attach the plurality of cylindrical rings along the common longitudinal

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axis thereby forming the longitudinally flexible stent." Claim 12 also requires a weld connection. The requester suggests that Fig. 1 of Furui clearly shows at least one weld connection. The examiner agrees with the declarant Jeffery Allen (see the declaration provided with the request) that Fig. 1 of Furui shows a globular mass connecting struts between adjacent rings and that this globular mass indicates the use of a filler material. See items 6 and 10 in the declaration. The examiner further agrees that the presence of the filler material excludes all of the types of joining mentioned in items 8 and 9, leaving only welding, brazing, or soldering. Finally, the examiner agrees that the joint shown is "welded." However, the examiner does not agree with Mr. Allen's explanation.

It is important to point out that the specification of the subject patent provides no guidance as to what is meant by "welding." See col. 3, l. 3, and the claims. Thus, "welding" must be given its plain meaning. See MPEP 2111.01.

The declarant, Mr. Allen, appears to be an ordinary skilled artisan due to his education and professional experience. See items 3 and 4 in the declaration. Thus, his opinion carries some weight as to the plain meaning of the term "welding" and what it encompasses.

In the declaration, at item 10, Mr. Allen averred that the joint could have been made by brazing or soldering, both of which are types of non-fusion welds, or any fusion weld utilizing the addition of a filler material. Here the examiner disagrees. According to the book Joining of Material and Structures, From Pragmatic Process to Enabling Technology¹, non-fusion welds are made without the use of a filler material that melts.

¹ Since the stents of the subject patent are metallic, it is appropriate to refer to general manuals or reference books on metals, such as this book, to determine the ordinary and customary meaning as understood by a person of ordinary skill in the art in question at the time of the invention, barring evidence in the record that the stent art uses other language for standard metal joining.

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See p. 332. Brazing and soldering are not types of non-fusion welds. See pp. 349, 392, and 393.

However, according to the same book, "In its broadest sense, welding includes any process that causes materials to join through the attractive action of interatomic or intermolecular forces, as opposed to purely macroscopic or even microscopic mechanical interlocking forces. Thus, welding ..., brazing ..., soldering ..., and even adhesive bonding ... can all be considered 'welding' processes by the preceding definition." See p. 285. This same book refers to brazing and soldering as subclassifications of welding. See pp. 351 and 391. Thus, since the joint shown in Furui is made by brazing, soldering, or a fusion weld utilizing a filler material, and brazing and soldering are subclassifications of welding, the joint is necessarily a welded joint.

16. Regarding claims 2-5, see Fig. 1.
17. Regarding claim 6, in the same manner as item 5 above, the connected portions of Fig. 1 of Furui are both "peaks."
18. Regarding claim 7, see Fig. 1.
19. Regarding claim 12, Fig. 1 shows out of phase rings. In the same manner as item 5 above, the connected portions of Fig. 1 of Furui are both "peaks," and the peaks of one ring point toward the peaks of the adjacent ring.
20. Regarding claims 13-15, see pg. 665, col. 3, l. 3.
21. Regarding claim 16, the language "one of N-1 adjacent weld connections" is not exclusive. Since Wolff discloses two weld connections between adjacent rings, Furui necessarily discloses one weld connection between adjacent rings.

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Response to Requester's Proposed Rejections

22. At pages 20-26 of the request, the requester suggests that both US Patent No. 5,133,732 to Wiktor ("Wiktor") and US Patent No. 4,733,665 to Palmaz ("Palmaz") anticipate claims 1-3. The examiner disagrees because both Wiktor and Palmaz do not disclose a plurality of cylindrical rings. With respect to this claim requirement, the requester relies on Fig. 7 of Wiktor (see p. 20 of the request) and Fig. 2B of Palmaz (see p. 24 of the request). However, Fig. 7 of Wiktor shows one continuous spiral and not a plurality of rings. Elongate members 78 and 79 in Fig. 2B of Palmaz do not amount to a plurality of rings. At page 4 of the decision ordering reexamination, the examiner stated Wiktor discloses a plurality of rings. However, upon reconsideration, the examiner now concedes that construing randomly chosen sections of a coil as a plurality of cylindrical rings, as shown in the figure at page 20 of the request, is not a reasonable position to take.

Statement of Reasons for Patentability and/or Confirmation

23. The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

24. Regarding **claim 8**, the prior art of record does not disclose, singly or in combination, the combination of elements recited in claim 8 including the weld connections attaching adjacent cylindrical rings being circumferentially aligned along the longitudinal axis.

25. Regarding **claims 9 and 10**, the prior art of record does not disclose, singly or in combination, the combination of elements recited in claim 9 including only one weld connection attaching adjacent cylindrical elements to each other.

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26. Regarding **claim 17**, the prior art of record does not disclose, singly or in combination, the combination of elements recited in claim 17 including each weld connection being circumferentially offset from the adjacent weld connections.
27. Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 6,066,168 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Any paper filed with the Office, *i.e.*, any submission made, by either the patent owner or the third party requester **must** be served on every other party in the reexamination proceeding in the manner provided by § 1.248. The document must

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reflect service or the document may be refused consideration by the Office. See 37 CFR 1.550(f).

The patent owner is notified that any proposed amendments to the specification and/or claims in this reexamination proceeding **MUST** comply with 37 CFR 1.530(d)-(j), 37 CFR 1.52(a) and (b), and 37 CFR 1.20(c).

Contact Information

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:


By U.S. Postal Service Mail: Mail Stop *Ex Parte* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-9900
Central Reexamination Unit

By hand: Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:


Sara Clarke
Primary Examiner
Central Reexamination Unit
(571) 272-4873





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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,889	01/23/2006	6066167	067448-0000004	5305

24201 7590 12/21/2006

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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED: 12/21/2006

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REEXAMINATION CONTROL NO. 90/007,889.

PATENT NO. 6066167.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

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Office Action in Ex Parte Reexamination	Control No. 90/007,889	Patent Under Reexamination 6066167	
	Examiner Sara S. Clarke	Art Unit 3993	

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a ☐ Responsive to the communication(s) filed on _____. b ☐ This action is made FINAL.

c ☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

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Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892. 3. ☐ Interview Summary, PTO-474.

2. ☒ Information Disclosure Statement, PTO/SB/08. 4. ☐ _____

Part II SUMMARY OF ACTION

1a. ☒ Claims 1-8 are subject to reexamination.

1b. ☐ Claims _____ are not subject to reexamination.

2. ☐ Claims _____ have been canceled in the present reexamination proceeding.

3. ☐ Claims _____ are patentable and/or confirmed.

4. ☒ Claims 1-8 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ The drawings, filed on _____, are acceptable.

7. ☐ The proposed drawing correction, filed on _____, has been (7a) ☐ approved (7b) ☐ disapproved.

8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have

1 ☐ been received.

2 ☐ not been received.

3 ☐ been filed in Application No. _____.

4 ☐ been filed in reexamination Control No. _____.

5 ☐ been received by the International Bureau in PCT application No. _____.

* See the attached detailed Office action for a list of the certified copies not received.

9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

10. ☐ Other: _____

cc: Requester (if third party requester)

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Page 1

DETAILED ACTION

Statutory Bases for Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. **Claims 1-8** are rejected under 35 U.S.C. 102(b) as being anticipated by the Mirich journal article "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" ("Mirich").

2. Regarding claims 1 and 5, Mirich discloses the invention as claimed including a longitudinally flexible stent. As discussed at pg. 1033, col. 2, bottom paragraph, of Mirich, self-expanding Gianturco stents are used in tandem. Since the Gianturco stents are self-expanding, it follows that the individual stents, used in tandem, are flexible such that the six-tip zig-zag pattern of the Gianturco stents flattens out upon expansion. Due to this flexibility within the individual Gianturco stents, the overall device comprising tandem Gianturco stents is necessarily longitudinally flexible, at least to some degree.

At pg. 1033, col. 2, bottom paragraph, Mirich further discloses the use of four Gianturco stents in tandem thus meeting the requirement for a first cylindrically shaped

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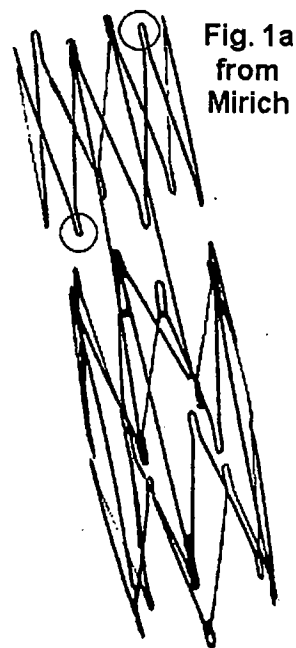
element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, and other than the first and the Nth cylindrically shaped elements, each of the cylindrically shaped elements has two adjacent cylindrically shaped elements spaced in opposite axial directions. As shown in Fig. 1b, the cylindrically shaped elements are generally independently expandable in the radial direction. As shown in Figs. 1a-c, the cylindrically shaped elements are generally aligned on a common longitudinal axis. As shown in Fig. 1a, each of the cylindrically shaped elements has an undulating pattern of peaks and valleys, the undulating pattern of each of the cylindrically shaped elements being out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements. Finally, Fig. 1a shows each of the cylindrically shaped elements being interconnected (via struts) to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent.

3. Regarding claims 2 and 6, see Fig. 1a, especially the bottom two stents.

4. Regarding claims 3 and 7, see Fig. 1a.

5. Regarding claims 4 and 8, Fig. 1a, as annotated by the examiner, includes circles around an exemplary peak and valley. As shown in the figure, the peaks and valleys of the stents are substantially U-shaped.

6. **Claims 1-8** are rejected under 35 U.S.C. 102(b) as being anticipated by the Furui article "Hepatic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents"



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("Furui").

7. Regarding claims 1 and 5, Furui discloses a longitudinally flexible stent as shown in Fig. 2c. Fig. 2c shows multiple stents in tandem conforming to the curve of a curved vessel. As shown in Fig. 1, Furui discloses a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element, the cylindrically shaped elements being generally aligned on a common longitudinal axis; other than the first and the Nth cylindrically shaped elements, each of the cylindrically shaped elements has two adjacent cylindrically shaped elements spaced in opposite axial directions; each of the cylindrically shaped elements having an undulating pattern of peaks and valleys, the undulating pattern of each of the cylindrically shape elements being out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements; and each of the cylindrically shaped elements being interconnected (via struts) to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent. Finally, Furui discloses the cylindrically shaped elements being generally independently expandable in the radial direction. Furui discloses that the individual cylindrical elements are Gianturco stents. As disclosed in U.S. Patent No. 5,305,706 to Gianturco et al. (cited in the IDS submitted May 30, 2006), a Gianturco stent is formed of a stainless steel wire arranged in a closed, zig-zag pattern, and is more fully described in US Pat. No. 4,580,568 to Gianturco (cited in the same IDS). Since the individual cylindrical elements are Gianturco stents, which expand upon removal of the sheath, and they are connected at only two opposite circumferential locations, the individual cylindrical elements of Furui appear to expand independently at least to some

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degree.

8. Regarding claims 2, 3, 6, and 7, see Fig. 1 of Furui.

9. Regarding claims 4 and 8, see Fig. 1. In the same manner as Mirich above (see item 5 above), the peaks and valleys shown in this figure are U-shaped.

10. **Claims 1, 3, 5, and 7** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,104,404 to Wolff ("Wolff").

11. Regarding claims 1 and 5, Wolff discloses the invention as claimed including a longitudinally flexible stent. Fig. 2 of Wolff shows the stent in a longitudinally flexed position. Wolff also discloses a first cylindrically shaped element, a second cylindrically shaped element, a third cylindrically shaped element, up to an Nth cylindrically shaped element and other than the first and the Nth cylindrically shaped elements, each of the cylindrically shaped elements has two adjacent cylindrically shaped elements spaced in opposite axial directions. Figs. 1-5 of Wolff show three stent segments 12. Moreover, at col. 1, ll. 59-61, Wolff discloses, "A relatively small number of stent segments are shown in the example but as many segments as may be required can be attached together using this approach." Thus, Wolff shows 1, 2, 3, ... N cylindrical elements and other than the first and the Nth cylindrically shaped elements, each of the cylindrically shaped elements has two adjacent cylindrically shaped elements spaced in opposite axial directions. Wolff further discloses the cylindrically shaped elements being generally independently expandable in the radial direction. Fig. 6 shows that the stent segments are capable of expanding independently to fit in a vessel having a change in diameter. Fig. 1 shows that the cylindrical elements are generally aligned on a common longitudinal axis. Fig. 1 shows each of the cylindrically shaped elements having an

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undulating pattern of peaks and valleys, the undulating pattern of each of the cylindrically shape elements being out of phase with the undulating pattern of each of the adjacent cylindrically shaped elements. Finally, Fig. 1 shows each of the cylindrically shaped elements 12 being interconnected (via hinges 14) to one of the adjacent cylindrically shaped elements so that the cylindrically shaped elements form a longitudinally flexible stent.

12. Regarding claims 3 and 7, see Fig. 1.

Response to Requester's Proposed Rejections

13. At pgs. 18-22 of the request, the requester suggests that the Wallace article "Tracheobronchial Tree: Expandable Metallic Stents Used in Experimental and Clinical Applications" ("Wallace"), anticipates claims 5 and 8. In making this suggesting, the requester refers to pg. 312 (third column) of Wallace, which states, "The stainless steel stent can be fashioned as to expansile properties, length, and diameter to suit the specific requirements." The requester then states, "Wallace implicitly recognizes that up to an Nth cylindrical element could be used." The examiner disagrees. By stating that the stent can be fashioned as to length to suit specific requirements, Wallace implies only that longer or shorter stents can be used. Without more, one skilled in the art cannot reasonably be expected to draw from Wallace any sort of inference as to how longer stents is achieved.

14. At pgs. 22-25 of the request, the requester suggests that Wolff anticipates claim 8. The examiner disagrees. Claim 8 requires that the peaks and valleys are U-shaped. The peaks and valleys of the stent segments disclosed by Wolff come to points and are thus V-shaped and not U-shaped.

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15. At pgs. 25-31 of the request, the requester suggests that EP Patent App. 357,003 A2 to Corvita Corporation ("Corvita") and the Trent journal article "A Balloon-Expandable Intravascular Stent for Obliterating Experimental Aortic Dissection" ("Trent") anticipate claims 5 and 8. The examiner disagrees because both of these reference fail to disclose even two cylindrical shaped elements, let alone more than three (*i.e.*, first, second, third, up to an Nth). The requester relies on Fig. 3 of Corvita (see page 25 of the request) and the disclosure of Trent at pg. 707 of a "continuous, complex coil cut to the length needed at the time of insertion" (see pg. 29 of the request). However, Fig. 3 of Corvita shows one continuous spiral and not a plurality of elements. Likewise, as noted by the requester, Trent also discloses a continuous spiral. At pgs. 6 and 7 of the decision ordering reexamination, the examiner stated that Fig. 3 of Corvita shows a plurality of sections and that Trent shows sections in the same manner as Corvita. However, upon reconsideration, the examiner now concedes that construing randomly chosen sections of a coil as a plurality of cylindrical shaped elements, as suggested by the requester, is not a reasonable position to take.

Conclusion

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR

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1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 6,066,167 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Any paper filed with the Office, *i.e.*, any submission made, by either the patent owner or the third party requester **must** be served on every other party in the reexamination proceeding in the manner provided by § 1.248. The document must reflect service or the document may be refused consideration by the Office. See 37 CFR 1.550(f).

The patent owner is notified that any proposed amendments to the specification and/or claims in this reexamination proceeding **MUST** comply with 37 CFR 1.530(d)-(j), 37 CFR 1.52(a) and (b), and 37 CFR 1.20(c).

Contact Information

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By U.S. Postal Service Mail: Mail Stop *Ex Parte* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-9900
Central Reexamination Unit


By hand: Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria, VA 22314

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Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:



Sara Clarke
Primary Examiner
Central Reexamination Unit
(571) 272-4873





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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,878	01/17/2006	5515154	067448-0000004	1031

24201 7590 12/21/2006

FULWIDER PATTON
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 10TH FLOOR
 LOS ANGELES, CA 90045

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED: 12/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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***EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM**

REEXAMINATION CONTROL NO. 90/007,878.

PATENT NO. 5515154.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/007,878	Patent Under Reexamination 5515154	
	Examiner Sara S. Clarke	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

- a ☐ Responsive to the communication(s) filed on _____. b ☐ This action is made FINAL.
c ☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892. 3. ☐ Interview Summary, PTO-474.
2. ☒ Information Disclosure Statement, PTO/SB/08. 4. ☐ _____

Part II SUMMARY OF ACTION

- 1a. ☒ Claims 1-23 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☒ Claims 6, 7 and 16 are patentable and/or confirmed.
4. ☒ Claims 1-5, 8-15 and 17-23 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a) ☐ approved (7b) ☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have
1 ☐ been received.
2 ☐ not been received.
3 ☐ been filed in Application No. _____.
4 ☐ been filed in reexamination Control No. _____.
5 ☐ been received by the International Bureau in PCT application No. _____.
* See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

U.S. Patent and Trademark Office
PTOL-466 (Rev. 08-06)

Office Action in Ex Parte Reexamination

Part of Paper No. 20060919

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DETAILED ACTION

Statutory Bases for Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 1-3, 8-11, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,922,905 to Strecker ("Strecker") in view of EP Patent App. 540,290 A2 to Advanced Cardiovascular Systems ("ACS").
2. The subject matter of claims 1 and 23 of the subject patent is not fully supported by the parent applications. More specifically, the parent applications do not provide support for the following recitation in claims 1 and 23 of the subject patent: "a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter." Thus, claim 1, the claims that depend thereon,

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and claim 23 are not entitled to the benefit of the filing date of the parent applications.

ACS was published (May 5, 1993) more than one year prior to the filing date of application, which matured into the subject patent. Since claims 1-11 and 23 are not entitled to the effective filing date of the parent applications, ACS is applicable against these claims under 35 U.S.C. 102(b). See MPEP 201.11(I)(B).

3. Regarding claim 1, Strecker discloses the invention substantially as claimed including an outer wall surface at 30' on a cylindrical element 20', said outer wall surface being smooth prior to expansion of said stent (Fig. 8) and forming a plurality of outwardly projecting edges 34 (Fig. 9) which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. See col. 9, ll. 17-21.

4. Regarding claims 2 and 3, see col. 9, ll. 14-21, and Figs. 8 and 9.

5. Regarding claim 8, see col. 8, ll. 33-38, which discloses that the configuration of Figs. 8 and 9 is fixable at a predetermined expansion site.

6. Regarding claim 11, see col. 3, l. 60.

7. Regarding claim 23, Strecker discloses an outer wall surface having a plurality of outwardly projecting edges 34 (Fig. 9) which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. See col. 9, ll. 17-21.

8. Strecker does not disclose a plurality of cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis; and a plurality of connecting elements for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other, as is required in claims 1 and 23. Strecker further does not disclose said stent being formed of a

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biocompatible material selected from the group of materials consisting of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers (claim 9); and said stent being formed from a single piece of tubing (claim 10).

9. ACS discloses a plurality of cylindrical elements 12 which are independently expandable in the radial direction. See col. 5, ll. 7 and 8. As disclosed in the abstract, ll. 5-8, elements 12 are interconnected so as to be generally aligned on a common longitudinal axis. ACS further discloses a plurality of connecting elements 13 for interconnecting said cylindrical elements 12, said connecting elements 13 configured to interconnect only said cylindrical elements 12 that are adjacent to each other. See col. 4, ll. 36 and 37. As discussed at col. 1, l. 51- col. 2, l. 14, the configuration of ACS, including independently expandable cylindrical elements 12 and connecting elements 13, results in a structure, which is both flexible along its length and stiff in the radial direction such that it is able to resist collapse.

10. ACS also teaches making its tubing of stainless steel, tantalum, NiTi alloys, and thermoplastic polymers because these materials are biocompatible. See col. 7, ll. 23-26.

11. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of Strecker, including its outwardly projecting edges, such that it has a plurality of independently expandable cylindrical elements, each interconnected only to adjacent cylindrical elements by connecting elements, as taught by ACS for the purpose of providing a structure, which is both flexible along its length and stiff in the radial direction such that it is able to resist collapse; and such that it has is made of stainless steel, tantalum, NiTi alloys, or thermoplastic polymers because these materials are biocompatible.

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12. **Claims 1, 4, 5, 8-10, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over ACS in view of Strecker.

13. Regarding claim 1, ACS discloses the invention substantially as claimed including a plurality of cylindrical elements 12 which are independently expandable in the radial direction (col. 5, ll. 7 and 8) and which are interconnected so as to be generally aligned on a common longitudinal axis (see Fig. 4); a plurality of connecting elements 13 for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other (see Fig. 4); and an outer wall surface on said cylindrical elements. As discussed at col. 2, l. 12, the configuration of ACS is flexible along its length.

14. Regarding claims 4 and 5, see Fig. 5.

15. Regarding claim 8, see col. 2, ll. 47-52.

16. Regarding claim 9, see col. 7, ll. 24-26.

17. Regarding claim 10, see the abstract, l. 4 and col. 3, ll. 3-6.

18. Regarding claim 23, ACS discloses a plurality of cylindrical elements 12 which are independently expandable in the radial direction (col. 5, ll. 7 and 8) and which are interconnected so as to be generally aligned on a common longitudinal axis (see Fig. 4); a plurality of connecting elements 13 for interconnecting said cylindrical elements, said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other (Fig. 4); an outer wall surface on said cylindrical elements, said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter, whereby said stent does not substantially shorten upon expansion from said first diameter

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to said second, larger diameter (col. 3, ll. 10-15).

19. ACS does not disclose said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter (claim 1) and said outer wall surface having a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter (claim 23).

20. Strecker discloses an outer wall surface at 30' on a cylindrical element 20', said outer wall surface being smooth prior to expansion of said stent (Fig. 8) and forming a plurality of outwardly projecting edges 34 (Fig. 9) which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. See col. 9, ll. 17-

21. The formation of outwardly projecting edges 34 assures a form-fit fixation of the endoprosthesis in the vessel wall. See col. 9, ll. 19-21.

21. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of ACS, such that it has outwardly projecting edges, which form as the stent is radially expanded, as taught by Strecker for the purpose of 34 assuring a form-fit fixation of the endoprosthesis in the vessel wall.

22. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over ACS as modified by Strecker, as applied to claim 1 above, and further in view of US Patent No. 3,126,005 to Bokros et al. ("Bokros").

23. As discussed at paragraphs 12-21 above, ACS and Strecker disclose the invention of claim 1 substantially as claimed. However, ACS does not disclose said stent being coated with a biocompatible coating and Strecker does not provide a motivation for

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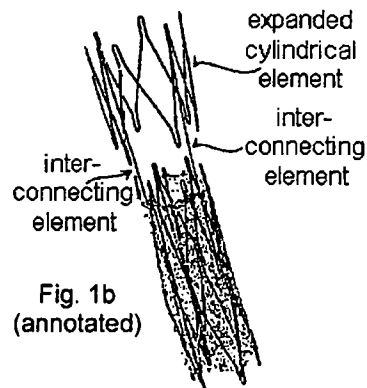
providing the stent of ACS with a biocompatible coating.

24. Bokros discloses an intravascular prosthesis having an impervious isotropic pyrolytic carbon coating. As described at col. 4, ll. 47-49, the coating is biocompatible. As described at the Abstract, the coating contributes substantial strength to the composite prosthetic device.

25. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of ACS, as modified by Strecker, to include a coating as taught by Bokros for the purpose of strengthening the device.

26. Claims 1, 3, 4, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Mirich journal article "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" ("Mirich") in view of the Rösch journal article "Experimental Intrahepatic Portacaval Anastomosis: use of Expandable Gianturco Stents" ("Rösch").

27. Regarding claim 1, Mirich discloses the invention substantially as claimed including a plurality of cylindrical elements (see Fig. 1) which are independently expandable in the radial direction (see Fig. 1b) and which are interconnected so as to be generally aligned on a common longitudinal axis (see Fig. 1); a plurality of connecting elements for inter-connecting said cylindrical elements (see Fig. 1b, annotated), and said connecting elements configured to interconnect only said cylindrical elements that are adjacent to each other; and an outer wall surface on said cylindrical elements.



28. Regarding claim 4, see Figs. 1a-c.

29. Regarding claim 9, see pg. 485, col. 1, l. 36.

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30. Mirich does not disclose said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. Nor does Mirich show the outwardly projecting edges extending radially outwardly from the outer wall.

31. Rösch discloses said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. As noted at pg. 482, first column, the stent shown in Rösch is introduced within a sheath. The sheath is removed and the stent expands. In the sheath, the stent is unexpanded and is "smooth" since the skirt and the remainder of the stent are restrained to the same diameter by the sheath. Upon removal of the sheath, as per the description at pg. 482, the stent expands. Figs. 2c and d show the stent without the sheath. The skirt has flared radially outwards such that the stent is no longer "smooth." That is, the skirt and the remainder of the stent no longer have the same diameter. As discussed at pg. 483, the use of a skirt helps to achieve proper positioning.

32. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of Mirich to include the skirts taught by Rösch such that the stent is smooth prior to expansion of said stent and forms a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter for the purpose of achieving proper positioning.

33. **Claims 1, 3, 4, and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirich in view of the Lawrence journal article "Percutaneous Endovascular Graft:

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Experimental Evaluation" ("Lawrence").

34. As noted at paragraphs 27-29 above, Mirich discloses the inventions of claims 1, 4, and 9 substantially as claimed. However, Mirich does not disclose said outer wall surface being smooth prior to expansion of said stent and forming a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. Nor does Mirich show the outwardly projecting edges extending radially outwardly from the outer wall.

35. Lawrence discloses an expandable stent having an outer wall surface, which is smooth prior to expansion of said stent and which forms a plurality of outwardly projecting edges, which edges form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter. As noted at pg. 357, third column, ll. 24-49, the grafts were introduced with the technique previously described for placement of a Gianturco stent (3)," making reference at footnote (3) to the Wright article "Percutaneous endovascular stents: an experimental evaluation." This article discloses the stent being compressed before introduction, and expanding after removal of said sheath. As noted at pg. 357 of Lawrence, second column, ll. 9-14 from the bottom, the stent shown in Lawrence is introduced within a sheath. The sheath is removed and the stent expands. See Fig. 1c. In the sheath, the stent is unexpanded and is "smooth" since the skirt and the remainder of the stent are restrained to the same diameter by the sheath. Upon removal of the sheath, as per the description at pg. 482, the stent expands. See pg. 357, second column, ll. 9-14 from the bottom, which disclose that after the device is released from the catheter, the internal stents open the Dacron tubing. Figs. 1b shows the stent without the sheath. The skirt has flared radially outwards such that the stent is no longer "smooth." That is, the

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skirt and the remainder of the stent no longer have the same diameter. As discussed at pg. 357, the use of a skirt helps to anchor the graft.

36. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of Mirich to include the skirts taught by Lawrence such that the stent is smooth prior to expansion of said stent and forms a plurality of outwardly projecting edges which form as said stent is expanded radially outwardly from a first diameter to a second, enlarged diameter for the purpose of achieving anchoring.

37. **Claims 12, 13, 17, 19, and 21** are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,104,404 to Wolff ("Wolff").

38. Wolff discloses the invention as claimed including a longitudinally flexible stent. Fig. 2 shows the stent flexed longitudinally. The articulated stent of Wolff comprises a plurality of cylindrical elements 12. Fig. 6 shows that the stent segments are capable of expanding independently to fit in a vessel having a change in diameter. Said elements 12 are interconnected (via hinges 14) so as to be concentrically aligned on a common longitudinal axis as shown in Fig. 1. A plurality of generally parallel connecting elements 14 interconnect said cylindrical elements. Fig. 1 of Wolff shows that the connecting elements 14 are configured to interconnect only said cylindrical elements that are adjacent to each other.

39. Claim 12 further requires that the connecting elements are configured to interconnect only said cylindrical elements that are adjacent to each other, so that said stent, when expanded radially outwardly, retains its overall length without appreciable shortening. The specification of the subject patent provides the following guidance regarding the configuration of connecting elements that causes the stent to retain its

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overall length without appreciable shortening when the stent is expanded radially outwardly. At the very bottom of col. and the top of col. 3, the subject patent discloses, "Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which for[m] the stent. In this manner there is no shortening of the stent upon expansion." At col. 5, ll. 48-51, subject patent discloses, "all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during expansion thereof." The subject patent makes no reference to any of the drawings to illustrate which particular configuration shows all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements. Since Wolff discloses its connecting elements 14 connected at only peaks and valleys, it appears that Wolff discloses identical structure to that disclosed in the subject patent for performing the claimed function. Thus, it appears that Wolff meets the limitation of having a configuration of connecting elements that causes the stent to retain its overall length without appreciable shortening when the stent is expanded radially outwardly.

40. Regarding claim 13, at per col. 1, ll. 54 and 55, Wolff discloses the use of the stent segments disclosed in US Patent No. 4,830,003 to Wolff et al. (" '003 patent"). When the stent elements in the '003 patent are released in position, they spring back to their normal, uncompressed position. See col. 3, ll. 1-18. Since the normal, uncompressed position is also the expanded position, the stent elements of Wolff are capable of retaining their expanded condition upon the expansion thereof.

41. Regarding claim 17, Fig. 1 shows the connecting elements are circumferentially

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displaced with respect to the longitudinal axis.

42. Regarding claim 19, Wolff discloses the use of a single hinge between adjacent cylindrical elements. This single hinge falls in the claimed range of up to four.

43. Regarding claim 21, since the product in this product-by-process claim is anticipated by the product of Wolff, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113 regarding product-by-process claims.

44. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,344,053 to Boneau ("Boneau") in view of Wolff.

45. Boneau discloses the invention substantially as claimed including a plurality of cylindrical elements (see col. 6, ll. 6-19) each having a diameter and a length. Claim 14 further requires that the radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof. At col. 5, ll. 4-22, Boneau discloses that the typical vessel, into which the stent of Boneau might be implanted ranges from 1.5 mm to 5 mm in diameter. Thus, since the cylindrical element of Boneau is expanded to the vessel diameter (see Fig. 4), the diameter of the cylindrical element of Boneau, upon inflation of the expandable member, ranges from 1.5 mm to 5 mm. Boneau also discloses that corresponding stents may range from 1 mm to 2 cm in length. Since Boneau discloses a range of diameters, which is greater than the disclosed range of lengths, it would have been obvious to one of ordinary skill in the art at the time of invention to make the stent of Boneau with the radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof. See MPEP 2144.05.

46. Regarding claim 15, Boneau discloses the use of stainless steel at col. 4, l. 48.

47. Boneau does not disclose a longitudinally flexible stent, comprising a plurality of

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interconnected cylindrical elements aligned along a common longitudinal axis, and upon radial expansion the stent retains its overall length without appreciable shortening, as required in claim 12.

48. Wolff discloses a longitudinally flexible stent arrangement having interconnected cylindrical elements aligned along a stent longitudinal axis as shown in Fig. 1. Based upon the structure disclosed in the subject patent for performing the function of not appreciably shortening upon radial expansion of the stent (see col. 3, ll. 9-13, and col. 5, ll. 53-56), which discloses connecting to either peaks or valleys, since the cylindrical elements of Wolff are connected by connectors at only peaks or valleys, it appears that the configuration of Wolff meets this functional limitation. As shown in Fig. 2, the arrangement of Wolff is longitudinally flexible. This arrangement, as described at col. 1, ll. 47-52, permits articulation and maintains the spacing between adjacent segments.

49. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the stent arrangement of Boneau with interconnections as taught by Wolff for the purpose of permitting articulation, maintaining the spacing between adjacent segments, and placing the tandem stents in vessels that curve in different directions.

50. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff.

51. Wolff discloses the invention substantially as claimed with the exception of the stent being formed from a single piece of tubing. Instead, Wolff discloses a plurality of welded together wires. However, as disclosed at col. 1, l. 55-58, the stent segments from '003 are merely illustrative. The subject patent does not attribute any new or unexpected results to forming the stent of a single piece of tubing. Thus, it would have been a matter of obvious design choice to one of ordinary skill in the art at the time of invention to make the device

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of Wolff of a single, integral piece since the subject patent does not attribute any new or unexpected results to forming the stent of a single piece of tubing. See MPEP 2144.04(V)(B).

52. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff in view of Bokros.

53. As discussed at item 38 and 39 above, Wolff discloses the invention of claim 12 substantially as claimed. However, Wolff does not disclose said stent being coated with a biocompatible coating.

54. Bokros discloses an intravascular prosthesis having an impervious isotropic pyrolytic carbon coating. As described at col. 4, ll. 47-49, the coating is biocompatible. As described at the Abstract, the coating contributes substantial strength to the composite prosthetic device.

55. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Wolff to include a coating as taught by Bokros for the purpose of strengthening the device.

56. **Claims 12 and 17-20** are rejected under 35 U.S.C. 102(b) as being anticipated by the Furui journal article "Hepatic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents" ("Furui").

57. Regarding claim 12, Furui discloses the invention as claimed including a longitudinally flexible stent as shown in Fig. 2c. Fig. 2c shows multiple stents in tandem conforming to the curve of a curved vessel. Furui further shows a plurality of cylindrical elements, which are independently expandable in the radial direction. Furui discloses that the individual cylindrical elements are Gianturco stents. As disclosed in U.S. Patent No.

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5,305,706 to Gianturco et al. (cited in the IDS submitted May 30, 2006), a Gianturco stent is formed of a stainless steel wire arranged in a closed, zig-zag pattern, and is more fully described in US Pat. No. 4,580,568 to Gianturco (cited in the same IDS). Since the individual cylindrical elements are Gianturco stents, which expand upon removal of the sheath, and they are connected at only two opposite circumferential locations, the individual cylindrical elements of Furui appear to expand independently at least to some degree. As shown in Fig. 1, the cylindrical elements of Furui are interconnected so as to be concentrically aligned on a common longitudinal axis. Since the cylindrical elements of Furui are connected by struts at only peaks or valleys, based upon the structure disclosed in the subject patent for performing the function of not appreciably shortening upon radial expansion of the stent (see item 39 above), it appears that the configuration of Furui meets this functional limitation.

58. Regarding claims 17-19, see Fig. 1 of Furui.

59. Regarding claim 20, see pg. 665, col. 2, last line and col. 3, ll. 4 and 5.

60. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Furui.

61. Claim 14 requires that the length of the radially expandable cylindrical elements in an expanded condition have a length less than the diameter thereof. Furui does not explicitly disclose a stent meeting this limitation. However, it does disclose stent segments having a length of 25 mm and a diameter range of 20-28 mm. See pg. 665, col. 2, last line and col. 3, first line. Since the claimed range of the diameter lies within the range disclosed by Furui, it would have been obvious to one of ordinary skill in the art at the time of invention to make the stent of Furui with the length of the radially expandable cylindrical

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elements in an expanded condition less than the diameter thereof. See MPEP 2144.05.

62. Regarding claim 15, see pg. 665, col. 2, last line.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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63. **Claims 1, 2, and 4** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of **US Patent No. 6,056,776**. Although the conflicting claims are not identical, they are not patentably distinct from each other because even though claims 6 and 7 of US Patent No. 6,506,776 do not recite an outer wall, the cylindrical rings of these claims inherently have outer wall surfaces. Moreover, since the projecting edges form upon expansion, by implication, prior to expansion, the outer wall surfaces are smooth since the projecting edges have not been formed. With respect to claim 4 of the subject patent, claims 6 and 7 of US Patent No. 6,506,776 recite an undulating pattern in the form of peaks and valleys, which is the same if not narrower than the claimed "serpentine pattern." Claims 6 and 7 of US Patent No. 6,056,776 do not recite the plurality of cylindrical elements being independently expandable, as recited in claim 1 of the subject patent. However, ACS teaches providing independently expandable cylindrical elements 12 to facilitate implantation of the stent in a variety of body lumen shapes. See col. 5, ll. 7-12. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of claims 6 and 7 of US Patent No. 6,506,776 to have independently expandable elements as taught by ACS for the purpose of facilitating implantation of the stent in a variety of body lumen shapes.

64. **Claims 1 and 2** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14, and 21 of **US Patent No. 5,728,158**. Although the conflicting claims are not identical, they are not patentably distinct from each other because every element recited in claims 1 and 2 of the subject patent is also recited in claims 1, 14, and 21 of US Patent No. 5,728,158 with the exception of the plurality of cylindrical elements being independently expandable, as recited in claim 1 of

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the subject patent. However, ACS teaches providing independently expandable cylindrical elements 12 to facilitate implantation of the stent in a variety of body lumen shapes. See col. 5, ll. 7-12. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the stent of 1, 14, and 21 of US Patent No. 5,728,158 to have independently expandable elements as taught by ACS for the purpose of facilitating implantation of the stent in a variety of body lumen shapes.

65. One-way obviousness analysis was applied above because it appears that the conflicting claims could have been filed in a single (*i.e.*, the earlier filed) application and it does not appear that there was an administrative delay. See MPEP 804(II)(B)(1)(a,b). However, in the event that the claims could not have been filed in a single application and there was administrative delay, the following rejection shows that claims 6 and 7 of US Patent No. 6,056,776 are obvious variations of the claims of the subject patent (two-way obviousness analysis).

66. Claims 6 and 7 of US Patent No. 6,056,776 are not patentably distinct from claim 4 of the subject patent because every element recited in claims 6 and 7 of US Patent No. 6,056,776 is also recited in claim 4 of the subject patent.

67. Claims 6 and 7 of US Patent No. 6,056,776 are not patentably distinct from claims 1 and 2 of the subject patent. Claims 1 and 2 of the subject patent do not recite an undulating pattern in the form of peaks and valleys. ACS discloses an undulating pattern in the form of peaks and valleys to provide for radial expansion by decreasing the wave's amplitude. See col. 2, ll. 28-43. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cylindrical elements of claims 1 and 2 of the subject patent such that the elements have an undulating pattern in the form of peaks and

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valleys as taught by ACS for the purpose of allowing radial expansion.

Response to Requester's Proposed Rejections

68. At pages 18-22 of the request, the requester suggests that the Mirich journal article "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" ("Mirich") anticipates claims 1 and 4. The examiner disagrees. The claim includes a comparison of the smoothness of the outer wall surface of the cylindrical elements in both expanded and non-expanded configurations. It appears from Figs. 1a-c that the stents of Mirich are "smooth" prior to expansion only by way of the nylon covering. The actual outer surface of the stents themselves, *i.e.*, not including the nylon covering, appears to be equally as "smooth" in both the expanded and non-expanded configurations. The so-called "projecting edges" the requester refers to at page 21 of the request appear, to the examiner, to exist equally in both the expanded and non-expanded configurations. Moreover, the "projecting edges" referred to by the requester are not outwardly projecting as required by claim 1. The requester also refers to the barbs of Fig. 1c. The examiner notes that in the embodiment of Fig. 1c, because of the barbs, the stents appear to be equally as smooth in both the expanded and non-expanded configurations.

69. At pages 30-32 of the request, the requester suggests that US Patent No. 5,133,732 to Wiktor ("Wiktor") anticipates claim 12. The examiner disagrees because Wiktor does not disclose a plurality of cylindrical elements and a plurality of generally parallel connecting elements. With respect to the requirement for a plurality of cylindrical elements, the requester relies on Fig. 12 (see page 30 of the request). However, this figure shows one continuous spiral and not a plurality of elements. At page 10 of the decision ordering reexamination, the examiner stated that Fig. 8 shows a plurality of

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sections. However, upon reconsideration, the examiner now concedes that construing randomly chosen sections of a coil as a plurality of cylindrical sections, as shown in the figure at page 10 of the decision, is not a reasonable position to take. With respect to the requirement for a plurality of generally parallel connecting elements, the first embodiment of Wiktor (Fig. 7) discussed by the requester at page 31, only shows one interconnected element. The second embodiment of Wiktor (Fig. 8), discussed by the requester at page 31, does not appear to show generally parallel connecting elements.

Statement of Reasons for Patentability and/or Confirmation

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

70. Regarding **claims 6 and 7**, the prior art does not show, singly or in combination, the combination of elements recited in this claim including members tipping radially outwardly to form said outwardly projecting edges upon radial expansion of the stent.

71. Regarding **claim 16**, the prior art does not show, singly or in combination, the combination of elements recited in this claim including the connecting elements between adjacent elements being in axial alignment.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not

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to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,514,154 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Any paper filed with the Office, *i.e.*, any submission made, by either the patent owner or the third party requester **must** be served on every other party in the reexamination proceeding in the manner provided by § 1.248. The document must reflect service or the document may be refused consideration by the Office. See 37 CFR 1.550(f).

The patent owner is notified that any proposed amendments to the specification and/or claims in this reexamination proceeding **MUST** comply with 37 CFR 1.530(d)-(j), 37 CFR 1.52(a) and (b), and 37 CFR 1.20(c).

Contact Information

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By U.S. Postal Service Mail: Mail Stop *Ex Parte* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents

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P. O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-9900
Central Reexamination Unit

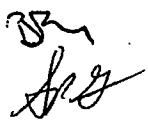
By hand: Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulany Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:



Sara Clarke
Primary Examiner
Central Reexamination Unit
(571) 272-4873





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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/007,888	01/23/2006	6432133	067448-0000004	1233

24201 7590 12/21/2006

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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED: 12/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/007,888.

PATENT NO. 6432133.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/007,888	Patent Under Reexamination 6432133	
	Examiner Sara S. Clarke	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a ☐ Responsive to the communication(s) filed on _____. b ☐ This action is made FINAL.

c ☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892. 3. ☐ Interview Summary, PTO-474.

2. ☒ Information Disclosure Statement, PTO/SB/08. 4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims 1-15 are subject to reexamination.

1b. ☐ Claims _____ are not subject to reexamination.

2. ☐ Claims _____ have been canceled in the present reexamination proceeding.

3. ☒ Claims 10, 11 and 15 are patentable and/or confirmed.

4. ☒ Claims 1-9 and 12-14 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ The drawings, filed on _____ are acceptable.

7. ☐ The proposed drawing correction, filed on _____ has been (7a) ☐ approved (7b) ☐ disapproved.

8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have

1 ☐ been received.

2 ☐ not been received.

3 ☐ been filed in Application No. _____.

4 ☐ been filed in reexamination Control No. _____.

5 ☐ been received by the International Bureau in PCT application No. _____.

* See the attached detailed Office action for a list of the certified copies not received.

9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

10. ☐ Other: _____

cc: Requester (if third party requester)

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DETAILED ACTION

Statutory Bases for Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 1-9 and 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,344,053 to Boneau ("Boneau") in view of US Patent No. 5,104,404 to Wolff ("Wolff").
2. Regarding claim 1, Boneau discloses the invention substantially as claimed including a plurality of cylindrical elements (col. 6, ll. 6-19) each having a diameter and a length. Each cylindrical element has a shape configured to enable the cylindrical element to expand with the inflation of an expandable member disposed therein. See the description at col. 5, ll. 40-52.

Claim 1 also requires that the length of each cylindrical element is less than 2.5

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mm. Boneau discloses that corresponding stents may range from 1 mm to 2 cm in length. Since the claimed length range of less than 2.5 mm overlaps the length range taught by Boneau, it would have been obvious to one of ordinary skill in the art at the time of invention to make the stent of Boneau in the claimed length range. See MPEP 2144.05.

Claim 1 further requires that length of each cylindrical element is less than the diameter of the cylindrical element upon inflation of the expandable member. Put another way, the diameter of the cylindrical element, upon inflation of the expandable member, is greater than or equal to 2.5 mm. At col. 5, ll. 4-22, Boneau discloses that the typical vessel, into which the stent of Boneau might be implanted, ranges from 1.5 mm to 5 mm in diameter. Since the cylindrical element of Boneau is expanded to the vessel diameter (see Fig. 4), the diameter of the cylindrical element of Boneau, upon inflation of the expandable member, ranges from 1.5 mm to 5 mm. Since the claimed range of greater than or equal to 2.5 mm overlaps the range of diameters disclosed by Boneau, it also would have been obvious to one of ordinary skill in the art at the time of invention to make the stent of Boneau in the claimed diameter range.

3. Regarding claim 3, Boneau shows U-shaped members at 12 and 14.
4. Boneau does not disclose a longitudinally flexible stent, comprising a plurality of interconnected cylindrical elements aligned along a stent longitudinal axis, as required in claim 1, and upon expansion there is no appreciable shortening of the stent, as required in claim 2.
5. Wolff discloses a longitudinally flexible stent arrangement having interconnected cylindrical elements aligned along a stent longitudinal axis as shown in Fig. 1.

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Regarding claim 2, based upon the structure disclosed in the subject patent for performing the function of not appreciably shortening upon radial expansion of the stent (see col. 3, ll. 9-13, and col. 5, ll. 53-56), which discloses connecting to either peaks or valleys, since the cylindrical elements of Wolff are connected by connectors at only peaks or valleys, it appears that the configuration of Wolff meets this functional limitation. Regarding claim 7, Wolff teaches offsetting connecting elements for the purpose of placing the stent in arteries that curve in two directions. See the top of col. 2. Regarding claims 9 and 14, Wolff further teaches the individual cylindrical elements being interconnected by at least one weld connection. See col. 3, ll. 46-48. As shown in Fig. 2, the arrangement of Wolff is longitudinally flexible. This arrangement, as described at col. 1, ll. 47-52, permits articulation and maintains the spacing between adjacent segments.

6. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to (a) provide the stent arrangement of Boneau with interconnections as taught by Wolff for the purpose of permitting articulation, maintaining the spacing between adjacent segments, and placing the tandem stents in vessels that curve in different directions; and (b) have made the cylindrical elements of Boneau in the claimed diameter and length ranges since the claimed ranges overlap the ranges disclosed by Boneau.

7. Regarding claims 4 and 12-14, since the product in this product-by-process claim is obvious from the product of Wolff and Boneau, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113 regarding product-by-process claims.

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8. Regarding claim 8, since Wolff teaches forming cylindrical elements individually (see Wolff, at col. 3, ll. 40-52), it follows that the stents resulting from the teachings of Boneau and Wolff, would also be formed individually. Moreover, since the product in this product-by-process claim is obvious from the product of Wolff and Boneau, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113 regarding product-by-process claims.

9. **Claims 1-3, 5, 6, 8, 9, and 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Boneau in view of the Furui article "Hepatic Inferior Vena Cava Obstruction: Treatment of Two Types with Gianturco Expandable Metallic Stents" ("Furui").

10. As discussed at items 2-4, Boneau discloses the invention substantially as claimed with the exception of a longitudinally flexible stent, comprising a plurality of interconnected cylindrical elements aligned along a stent longitudinal axis, as required in claim 1.

11. Furui discloses a longitudinally flexible stent comprising a plurality of interconnected cylindrical elements aligned along a stent longitudinal axis as shown in Fig. 1. As shown in Fig. 2c, the tandem stents of Furui are longitudinally flexible. As disclosed at page 669, col. 3, ll. 6-9, the use of tandem stents prevents slippage. Regarding claims 9 and 14, Fig. 1 appears to show weld connections for the struts.

12. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the stent arrangement of Boneau with interconnections as taught by Furui for the purpose of preventing slippage.

13. Regarding claim 2, based upon the structure disclosed in the subject patent for

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performing the function of not appreciably shortening upon radial expansion of the stent (see col. 3, ll. 9-13, and col. 5, ll. 53-56 in the subject patent), *i.e.*, connecting to either peaks or valleys, since the cylindrical elements of Furui are connected by struts at only peaks or valleys, it appears that the configuration of Furui meets this functional limitation.

14. Regarding claims 8 and 12, since the product in this product-by-process claim is obvious from the product of Furui and Boneau, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113 regarding product-by-process claims.

Response to Requester's Proposed Rejections

15. At pp. 19-27 of the request, the requester suggests that US Patent No. 4,856,516 to Hillstead ("Hillstead") anticipates claims 1-3 and 8 of the subject patent and renders claim 9 of the subject patent obvious (in view of US Patent No. 5,133,732 to Wiktor ("Wiktor")), Wolff, or US Patent No. 4,733,665 to Palmaz ("Palmaz"). The examiner disagrees. Claim 1 requires a plurality of interconnected cylindrical elements. While Hillstead appears to disclose a plurality of interconnected elements (loops 50, 50a, and 50b), it is unclear from the disclosure, including the drawings, whether loops 50, 50a, and 50b are cylindrical or not. That is, it is unclear from the drawings whether or not the bends (shown in Fig. 4) extend widthwise in the longitudinal direction or radially when the stent 10 is formed. Since it is unclear whether or not loops 50, 50a, and 50b are cylindrical or not, it cannot be said that Hillstead meets this claim limitation. Thus, Hillstead does not anticipate claim 1 or any of the claims that depend thereon. Moreover, Wiktor, Wolff, and Palmaz do not make up for the deficiencies of Hillstead.

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Thus, Hillstead, in combination with Wiktor, Wolff, or Palmaz, does not render claim 9 obvious.

16. At pp. 28-36 of the request, the requester suggests that SU Pub. No. 1457921 ("SU '921") in view of US Patent No. 6,344,053 to Boneau ("Boneau") and/or the Rösch article ("Modified Gianturco Expandable Wire Stents in Experimental and Clinical Use") renders claims 1-3 and 8 obvious, and SU '921 and Boneau and/or Rösch (in view of Wiktor, Wolff, or Palmaz) render claim 9 obvious. The examiner disagrees. All of SU '921, Boneau, and Rösch disclose endovascular support devices. However, with respect to SU '921, the requester refers to elements 3 and 4, which function as peripheral devices to the stent to prevent migration of the overall stent prosthesis. Whereas, with respect to Boneau, the requester refers to stents 10; and with respect to Rösch, the requester refers to the stent bodies (as shown in Fig. 1). Said stents 10 in Boneau and stent bodies in Rösch function to dilate narrowed vascular vessel. The dimensions taught by Boneau and Rösch are important for maintaining the axial orientation of the stent, extending across the affected area, and preventing undue thrombosis (See Boneau, col. 5, ll. 4-22) and, depending on the length of the vessel, for increasing the expansion force, especially in a curved vessel (See Rösch, page 101, col. 2, ll. 14-37). Since the reasons for providing the dimensions of Boneau and Rösch relate to problems associated with a stent device, and not a stent peripheral device for preventing migration (SU '921), there does not appear to be any reason for one of ordinary skill in the art to modify the migration preventing device of SU '921 to utilize the dimensions taught by Boneau and/or Rösch. Wiktor, Wolff, and Palmaz do not make up for the deficiencies of SU '921, Boneau, and Rösch. Thus, SU '921, Boneau, Rösch,

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Wiktor, Wolff, and Palmaz do not render claim 9 obvious.

17. At the bottom of pg. 37 and the top of page 43 of the request, the requester argues that Rösch teaches, "one of ordinary skill would appreciate that the smallest stent segment available would be desirable to provide for the increased flexibility necessary to provide treatment for more tortuously twisted vessels... The '133 patent's claims' explicit range limitation of 'having a length less than 2.5 mm...' merely represents a possible optimization of the invention disclosed by Rösch... In fact, Rösch provides all motivation necessary for one of ordinary skill in the art to minimize the stent segment length in order to achieve optimal flexibility." To the extent that this argument applies to the suggested rejections at pp. 36-48, the examiner feels that it is unnecessary to rely on the teachings of Rösch since a *prima facie* case of obviousness can be made with Boneau and Wolff or Furui, by themselves. Moreover, it is unclear how Rösch is relevant. Rösch only suggests shorter lengths when the overall length of the stent is greater than 4 cm. Since the lengths disclosed by Boneau are considerably shorter than 4 cm, there does not appear to be a suggestion to use a shorter length. That is, the tandem configuration of Rösch, as shown in Fig. 1F, and including shorter stent bodies connected end-to-end via a monofilament line, is so disparate from the configurations of Wolff and Furui, it is unclear how the discussion at p. 101, col. 2, ll. 20-25 is relevant to consideration of size optimization of the elements 12 in Wolff, which are connected by hinges 14, and the elements shown in Fig. 1 of Furui. Moreover, since the length of 2 cm disclosed by Rösch is much longer than the claimed range of less than 2.5 mm, it is unclear how this disclosure generally suggests the claimed range.

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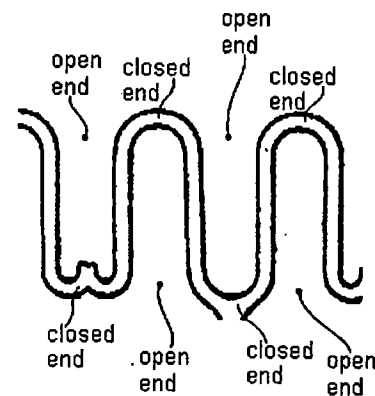
Statement of Reasons for Patentability and/or Confirmation

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

18. Regarding **claims 10 and 11**, while both Wolff and Furui disclose in-phase and out-of-phase adjacent elements, respectively, they provide no reasons for providing such configurations. As such there is no motivation to modify Boneau to include these features.

19. Regarding **claim 15**, not finding any guidance in the specification as to the meaning of the terms "open ends" and "closed ends" as used in this claim, the examiner finds that there are two possible interpretations for "open ends" and "closed ends":

(a) Looking at the undulating pattern of the stent portions (see the cropped section taken from Fig. 5 of the subject patent, at right), the "closed ends" could refer to the U, Y, or W shaped portions of the undulating pattern, and the "open ends" could refer to the opposite ends from the closed ends; or



(b) Based on the disclosure of the subject patent, the "open ends" could refer to the circumferential openings of a single undulating portion and the "closed ends" could refer to the cylindrical outer wall defined by a single undulating portion. Claim 15 compares the dimensions of the "open ends" and the "closed ends." Looking at the specification, the only comparison of dimensions is found at col. 2, ll. 4-6, comparing the length and diameter.

Based on either interpretation, the prior art of record does not appear to disclose

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at least one of the open ends being no wider than one of the closed ends when the stent is mounted on an expandable member before expansion, as required in claim 15.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

Extensions of time under 37 CFR 1.136(a) will **not** be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 6,432,133 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Any paper filed with the Office, i.e., any submission made, by either the patent owner or the third party requester **must** be served on every other party in the reexamination proceeding in the manner provided by § 1.248. The document must reflect service or the document may be refused consideration by the Office. See 37

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CFR 1.550(f).

The patent owner is notified that any proposed amendments to the specification and/or claims in this reexamination proceeding **MUST** comply with 37 CFR 1.530(d)-(j), 37 CFR 1.52(a) and (b), and 37 CFR 1.20(c).

Contact Information

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:


By U.S. Postal Service Mail: Mail Stop *Ex Parte* Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
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Alexandria, VA 22313-1450

By FAX: (571) 273-9900
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By hand: Customer Service Window
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Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:



Sara Clarke
Primary Examiner
Central Reexamination Unit
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EXHIBIT L

90/007,878 EXPANDABLE STENTS

10-31-
2007::18:25:19

Bibliographic Data

Application Number:	90/007,878	Customer Number:	-
Filing or 371 (c) Date:	01-17-2006	Status:	Response after Non-Final Action Entered (or Ready for Examiner Action)
Application Type:	Re-Examination	Status Date:	03-26-2007
Examiner Name:	CLARKE, SARA SACHIE	Location:	ELECTRONIC
Group Art Unit:	3993	Location Date:	-
Confirmation Number:	1031	Earliest Publication No:	-
Attorney Docket Number:	067448-0000004	Earliest Publication Date:	-
Class / Subclass:	606/195	Patent Number:	-
First Named Inventor:	5514154 , ,	Issue Date of Patent:	-

Title of Invention: EXPANDABLE STENTS

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90/007,889 EXPANDABLE STENTS

10-31-
2007::22:34:25**Bibliographic Data**

Application Number:	90/007,889	Customer Number:	-
Filing or 371 (c) Date:	01-23-2006	Status:	Response after Non-Final Action Entered (or Ready for Examiner Action)
Application Type:	Re-Examination	Status Date:	03-26-2007
Examiner Name:	CLARKE, SARA SACHIE	Location:	ELECTRONIC
Group Art Unit:	3993	Location Date:	-
Confirmation Number:	5305	Earliest Publication No:	-
Attorney Docket Number:	067448-00000004	Earliest Publication Date:	-
Class / Subclass:	623/001	Patent Number:	-
First Named Inventor:	6066167 , ,	Issue Date of Patent:	-

Title of Invention: EXPANDABLE STENTS

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90/007,890 EXPANDABLE STENTS AND METHOD FOR MAKING SAME

10-31-
2007::21:59:16

Bibliographic Data

Application Number:	90/007,890	Customer Number:	-
Filing or 371 (c) Date:	01-23-2006	Status:	Response after Non-Final Action Entered (or Ready for Examiner Action)
Application Type:	Re-Examination	Status Date:	10-23-2007
Examiner Name:	CLARKE, SARA SACHIE	Location:	ELECTRONIC
Group Art Unit:	3993	Location Date:	-
Confirmation Number:	5461	Earliest Publication No:	-
Attorney Docket Number:	067448-0000004	Earliest Publication Date:	-
Class / Subclass:	623/001.160	Patent Number:	-
First Named Inventor:	6066168 , ,	Issue Date of Patent:	-

Title of Invention:	EXPANDABLE STENTS AND METHOD FOR MAKING SAME
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90/007,888 EXPANDABLE STENTS AND METHOD FOR MAKING SAME

10-31-
2007::23:00:36**Bibliographic Data**

Application Number:	90/007,888	Customer Number:	-
Filing or 371 (c) Date:	01-23-2006	Status:	Response after Non-Final Action Entered (or Ready for Examiner Action)
Application Type:	Re-Examination	Status Date:	03-25-2007
Examiner Name:	CLARKE, SARA SACHIE	Location:	ELECTRONIC
Group Art Unit:	3993	Location Date:	-
Confirmation Number:	1233	Earliest Publication No:	-
Attorney Docket Number:	067448-0000004	Earliest Publication Date:	-
Class / Subclass:	623/001.150	Patent Number:	-
First Named Inventor:	6432133 , ,	Issue Date of Patent:	-

Title of Invention: EXPANDABLE STENTS AND METHOD FOR MAKING SAME

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EXHIBIT M

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Analysis of Prolapse in Cardiovascular Stents: A Constitutive Equation for Vascular Tissue and Finite-Element Modelling

The effectiveness of a cardiovascular stent depends on many factors, such as its ability to sustain the compression applied by the vessel wall, minimal longitudinal contraction when it is expanded, and its ability to flex when navigating tortuous blood vessels. The long-term reaction of the tissue to the stent is also device dependant; in particular some designs provoke in-stent restenosis (i.e., regrowth of the occlusion around the stent). The mechanism of restenosis is thought to involve injury or damage to the vessel wall due to the high stresses generated around the stent when it expands. Because of this, the deflection of the tissue between the struts of the stent (called prolapse or "draping") has been used as a measure of the potential of a stent to cause restenosis. In this paper, uniaxial and biaxial experiments on human femoral artery and porcine aortic vascular tissue are used to develop a hyperelastic constitutive model of vascular tissue suitable for implementation in finite-element analysis. To analyze prolapse, four stent designs (BeStent 2, Medtronic AVE; NIROYAL, Boston Scientific; VELOCITY, Cordis; TETRA, Guidant) were expanded in vitro to determine their repeating-unit dimensions. This geometric data was used to generate a finite element model of the vascular tissue supported within a repeating-unit of the stent. Under a pressure of 450 mm Hg (representing the radial compression of the vessel wall), maximum radial deflection of 0.253 mm, 0.279 mm, 0.348 mm and 0.48 mm were calculated for each of the four stents. Stresses in the vascular wall were highest for the VELOCITY stent. The method is proposed as a way to compare stents relative to their potential for restenosis and as a basis for a biomechanical design of a stent repeating-unit that would minimize restenosis. [DOI: 10.1115/1.1613674]

1 Introduction

Blockage of the coronary artery (stenosis) is a major healthcare problem that defied effective solution until the introduction of a procedure called balloon angioplasty. Performed by an interventional cardiologist, the procedure involves advancing an angioplasty balloon to the stenosed site and inflating it to permanently deform the blockage and radially expand the vessel. Balloon angioplasty has the limitation that elastic recoil of the artery can occur and the vessel returns to near its pre-intervention diameter. To prevent such elastic recoil, cardiovascular stents were introduced to maintain vessel patency [1]—these devices are either balloon expanded [1] or self-expanding [2].

Issues with respect to the design of cardiovascular stents include: (i) sufficient rigidity to resist the compressive forces from the vessel wall, (ii) sufficient flexibility to navigate tortuous vessels, (iii) scaffolding properties: stents must be able to hold open the vessel and scaffold the stenotic material (plaque) against the vessel wall, (iv) minimal longitudinal contraction when expanded, (v) minimal shearing between the stent and tissue during expansion because this denudes the vessel of its endothelial cell lining. These five objectives are difficult, if not impossible, to meet in any one stent design. A further design objective may be added, viz (vi) minimal activation of the re-stenosis mechanism. Restenosis

occurs when the blockage reforms around the stent, usually in the form of neointimal hyperplasia [3]. In a clinical study of 4,510 stent placements, Kastrati et al. [4] showed that restenosis is related to stent design with more than 30% of procedures resulting in restenosis with several of the designs. Innovation in stent design to minimize restenosis while maintaining the design objectives [(i) to (v) above] would be facilitated by use of finite-element modelling for rapid investigation of design concepts prior to clinical trials.

Many analyses of the blood flow in vessels have correlated the local haemodynamics with the formation of plaque layers, particularly at the site of low wall shear stresses nearby vascular grafts. Because of this well-established relationship between fluid-generated wall shear stresses and the development of atherosclerosis, it has been postulated that fluid flow may also be responsible for the neointimal hyperplasia that occurs during in-stent re-stenosis. However, animal studies have clearly established a role for tissue damage due to the balloon and/or the stent in neointimal hyperplasia [5].

To date, finite-element models have focused on stent design parameters and not on restenosis, e.g. the analysis of stent shortening on expansion and the degree of elastic recoil as a function of expansion diameter [6], and deformations and stresses in a stent under flexion [7]; both of these studies ignored the blood vessel/stent interaction. The vessel was represented as a linear elastic material by Veress et al. [8] who analyzed the stress generated in the neighborhood of an atherosclerotic plaque layer and by Rogers et al. [9] who reported a 2-D finite-element analysis of a stent wire contacting with the vessel wall. Despite its simplified nature of this latter study, it did show that strut spacing influenced

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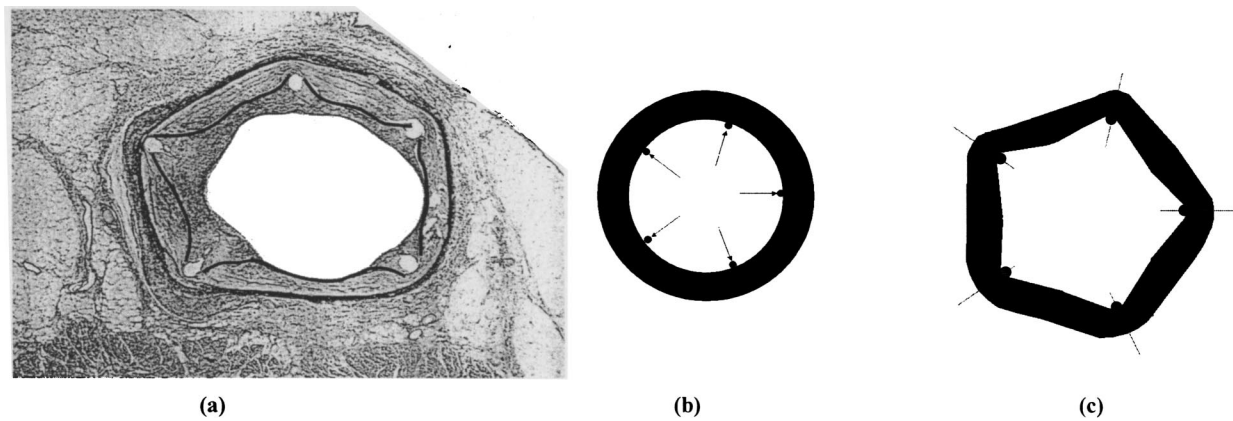


Fig. 1 (a) Luminal tissue prolapse within a stented vessel (indicated by black lines)¹, (b) A 2-D schematic of a stented vessel before stenting with vessel wall ideally cylindrical and (c) after stenting where the tissue drapes between the stent wires

¹From Schwartz et al., J Intervent Cardiol 7, 1994

stresses generated in the vessel wall [9]. Hayashi and Imai [10] presented a hyperelastic constitutive model of the vessel wall and plaque and calculated the stress distribution when the vessel was subjected to internal pressure.

Using a hyperelastic model of an incompressible isotropically elastic solid, the Cauchy stress, σ_{ij} , may be given in terms of the left Cauchy-Green tensor, B_{ij} , as:

$$\sigma_{ij} = -p + 2 \frac{\partial W}{\partial I_1} B_{ij} - 2 \frac{\partial W}{\partial I_2} B_{ij}^{-1}, \quad (1)$$

where W is the strain energy and I_1 , I_2 and I_3 are the invariants of B_{ij} [11]. If the principal stretches are denoted λ_1 , λ_2 and λ_3 then $I_1 = \lambda_1^2 + \lambda_2^2 + \lambda_3^2$, $I_2 = \lambda_1^{-2} + \lambda_2^{-2} + \lambda_3^{-2}$, and $I_3 = \lambda_1^2 \lambda_2^2 \lambda_3^2$. ($I_3 = 1$ if the tissue is incompressible; incompressible nature of vascular tissue was established by Carew et al. [12]). Hayashi and Imai [10] used the strain energy density function given in Eq. (2) to develop a constitutive model for the vessel wall based on measurements of vascular tissue under uniaxial tension:

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{02}(I_2 - 3)^2 + a_{03}(I_2 - 3)^3. \quad (2)$$

This form of the strain energy function may be most generally written as:

$$W = \sum_{i=0, j=0}^{\infty} a_{ij}(I_1 - 3)^i (I_2 - 3)^j, \quad a_{00} = 0, \quad (3)$$

see Mooney [13]. This Mooney-Rivlin form constitutive equation is included in several finite-element codes and is therefore readily applicable to stent design. The constants a_{ij} are obtainable from experimental tests which, ideally, should be conducted with similar deformation modes to those appearing in vivo. In the case of cardiovascular stents the tissue is stressed biaxially between the wires or slots of the stent as it expands and therefore the tests should include biaxial loading. Such devices have been presented before by several authors (see the review by Sacks [14]) either using transducers and feedback control to maintain an equi-biaxial force or using systems of levers.

In this paper, data was obtained for porcine aorta and human femoral arteries. The data obtained was used to develop the constitutive model for blood vessel tissue which was then used in a finite-element analysis to calculate vascular tissue deformation, or prolapse, within four commonly used stent designs. The word prolapse is used to refer to the lumen loss due to deflection of the tissue within the stent, see Fig. 1. Several clinical studies have associated prolapse with the appearance of re-stenosis [15–17]. If this is true, and since prolapse is likely to be related to stent design, it is expected that those stents that allow prolapse are also the ones that generate stresses causing damage to the vessel wall

and associated intimal hyperplasia. In this paper, we aim to investigate the relationship between prolapse, vessel wall stresses, and stent design. If it is found that stents have significantly different prolapse, then finite-element analysis could be used to design against in-stent re-stenosis by minimizing prolapse because that would reduce associated high vessel wall stresses that drive the restenosis process.

2 Methods

2.1 Tissue Testing. Porcine aorta from adult Landrace pigs (25 kg weight; 50 ml euthathol to induce death) and human femoral arterial tissue were used in the experiments. Samples were stored in antibiotic solution at 4°C until testing. All samples were prepared under sterile conditions, and any visible connective tissue was removed from the surface of the vessel before it was cut along its length, pressed flat, and sectioned. Lengths of tissue were prepared for uniaxial testing and areas of 25 mm square were prepared for biaxial testing. The thickness of each sample was measured with a Vernier calipers at several locations and an average taken. Each sample was marked to indicate its circumferential/longitudinal orientation. Both uniaxial and biaxial stress-stretch data were obtained as described in Sections 2.1.1 and 2.1.2 below. In both tests a strain rate of 60% per minute was used. Specimens were continuously irrigated with 0.9% saline solution during testing. Preconditioning of the samples was carried out to a maximum load of 1 N at a strain rate of 60%/min. There was a slight variation in the thickness of the specimens: femoral tissue specimen thicknesses were 1.5 ± 0.5 mm and the aortic specimen thicknesses were 2.5 ± 0.5 mm. The stress was determined in each case by dividing the load by the instantaneous cross sectional area and the stretch was obtained by dividing the instantaneous length by the original length.

2.1.1 Uniaxial Testing. Stainless steel grips with rubber coatings and emery paper to prevent slippage during loading were mounted on a 1011 Instron (displacement controlled) tensile testing machine. Specimens were longitudinal in the in vivo orientation. Extension of the specimen was taken to be the crosshead displacement. The tests were stopped when tearing began at either the grips or along the length of the specimen.

2.1.2 Biaxial Testing. The biaxial rig was designed so that it could be used on a standard uniaxial Instron 1011 testing machine and comprised a number of working assemblies as shown in Fig. 2. The suspension assembly consisted of four horizontal arms of equal length stemming from a central block secured to the crosshead of the testing machine. The four arms supported four identical balance beams—each beam was free to pivot on a polished

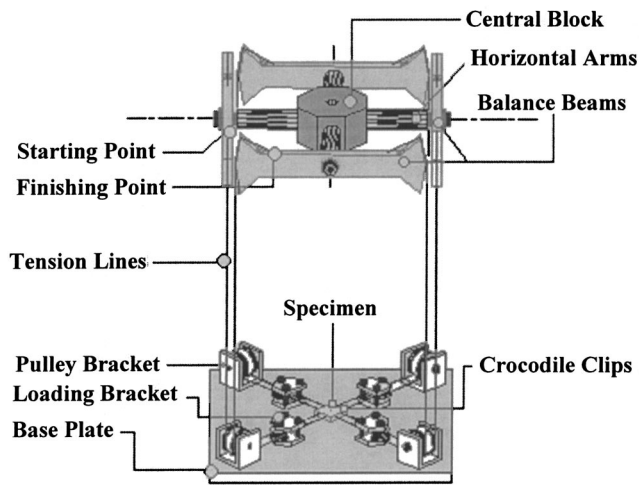


Fig. 2 Schematic illustration of the biaxial testing device

stainless steel shoulder screw. Oil-impregnated bushes were used to minimize frictional forces between the screws and the beams. The base plate was secured to the base of the testing machine. The base plate consisted of four brackets containing pairs of stainless steel pulleys. The main function of the bracket-pulley assemblies were to turn the vertical cable network through 90° and guide them toward the square specimen of cardiovascular tissue positioned centrally on the base plate. High-strength fishing line (50 lb breaking strain) was used for the cable network. The route of a line can be seen from Fig. 2; each line originated from a position on a balance beam and was guided along a curved groove at the end of the beam; this ensured that each line was in constant tension and remained perpendicular to the base plate assembly. Each line was suspended from the balance beam and passed through the pulley-bracket fixture on the base plate and was turned through 90° towards the central area of the base plate. Each line passed through a loading bracket before returning via a similar route to the end of the adjacent balance beam. The loading bracket transferred the loads from the line to the specimen. The jaw end of each crocodile clip was used to grip the sample and the other end was linked to a vertical dowel pin on the Perspex bracket.

For biaxial testing, a 3×3 array of dots was printed on the inner surface of the blood vessel using a rubber stamp and water resistant, oil-based, quick drying ink. A typical such sample is shown in Fig. 3. The distance between each dot was approximately 5 mm. Two crocodile clips were attached at each side as shown in

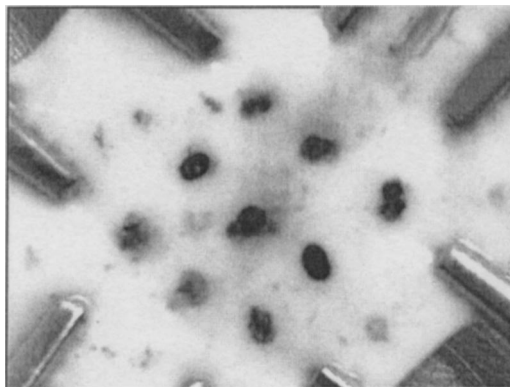


Fig. 3 Close-up view of a biaxial specimen with the array of dots used to measure stretch and the crocodile clips used to clamp the tissue

Fig. 3. The clips were adjusted to ensure that each jaw remained firmly locked during the test. The sample was then placed in the center of the rig and the metallic clips hooked between the Perspex loading brackets and the crocodile clips. The crosshead of the Instron was advanced until any slack was eliminated from the specimen. The tests were stopped when tissue tearing or slippage began at the jaws of the crocodile clips.

A digital camera mounted above the test specimen was used to take images of the tissue at set intervals during the test. Each image was edited to remove the background and to isolate the markers. The image was then thresholded and brought into UTH-SCSA Image Tool (University of Texas). The strain of the tissue in the principal directions was then determined from the movement of the centroid of these dots on the specimen from picture to picture as the load increased. The engineering stress was calculated by dividing the load by the initial cross-sectional area. For the biaxial tests, to obtain the parameters of the Mooney-Rivlin models, it was necessary to establish just one biaxial stress-stretch curve to define the material properties since the Mooney-Rivlin model assumes the material to be isotropic—therefore, an average stress-stretch curve was determined from the stress-stretch curves in both the circumferential and longitudinal directions.

2.2 Constitutive Modelling. The strain energy function W given in Eq. (3) can be expanded to obtain the special cases of the two, five or nine parameter strain energy density functions:

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) \quad (4)_1$$

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{02}(I_2 - 3)^2 \quad (4)_2$$

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{02}(I_2 - 3)^2 + a_{30}(I_1 - 3)^3 + a_{21}(I_1 - 3)^2(I_2 - 3) + a_{12}(I_1 - 3)(I_2 - 3)^2 + a_{03}(I_2 - 3)^3 \quad (4)_3$$

These equations represent first-, second-, and third-order models, respectively. When the expression given in $(4)_1$ is reduced to $W = a_{10}(I_1 - 3)$ it is called the neo-Hookean form of the strain energy function [18]. As the complexity of the expression for W is increased further deformation modes are more accurately modelled, in principle. (For example, it can be seen from Eq. $(4)_3$ that the expression of W used by Hayashi and Imai [10] [Eq. (2) above] is a third-order model that is special case of a nine-parameter Mooney-Rivlin model.) When a suitable form of the strain energy function is chosen, the parameters a_{ij} are found by nonlinear regression. In some cases, it may be found that the predicted nonlinear elasticity is unaffected by a particular parameter and therefore that parameter is redundant and may be set to zero. However, the final set of parameters must satisfy the requirement for positive definiteness of the elastic behavior, and these conditions can be violated if insufficient data is used in the regression [19,20].

2.3 Determination of Stent Expanded Shape. The stent measurements were obtained by taking pictures of the fully expanded stent under a LEICA MZAP0 microscope using a JVC digital 1/2 inch color CCD camera and LEICA QWIN standard software. A line of known length was incorporated into each image, which was determined from a calibration plate used with the microscope. The images were imported into WINDIG where coordinates, to define the cell area of each stent, were obtained by defining points on the stent wire. The coordinate values were then imported into ANSYS and projected onto a 3.5 mm diameter cylinder to define the geometry of one repeating unit of each stent design. Four stent designs were analyzed: (BeStent 2, Medtronic AVE, NIROYAL, Boston Scientific; VELOCITY, Cordis, and the TETRA, Guidant), see Fig. 4.

2.4 Finite-Element Modelling. Three-dimensional finite-element models of the arterial tissue within the stents were generated numerically using ANSYS Version 5.5 (Canonsburg, PA, USA). The element used was a 3-D 8-node isoparametric element (HYPER58, a mixed U-P hyperelastic solid element). Eight elements were employed through the thickness of the vessel wall. This choice was made based on the results of a mesh convergence study (see Appendix). The thickness of the arterial tissue in the numerical models was taken as 0.5 mm, based on the average thickness of the human coronary artery wall [21]. Figure 4 shows the finite-element mesh of each of the four repeating units. The models were restrained around the edges of the stent repeating-unit to represent the constraint of the stent wire. Such a restraint was considered to be adequate since the stent wire thickness (approximately 0.1 mm) is much less than the thickness of the tissue. To simulate the deformation of the vessel wall around the stent wires, consider that, in the ideal case, a cylindrical vessel [c.f. Fig. 1(b)] is deformed by the radial motion of the stent wires into a shape represented schematically in Fig. 1(c). The expanded vessel with a surface pressure applied to it will have a similar deformation to that illustrated in Fig. 1(c). According to Serruys and Kutryk [22], a maximum pressure a stent is expected to sustain in vivo is 450 mmHg (~60 kPa) and this value was applied to the vessel wall in the finite element model.

3 Results

3.1 Nonlinear Elastic Behavior and Constitutive Modelling. The elastic behavior of all tissues was found to be significantly nonlinear to high strains. It is noteworthy that significant variation occurs in the elastic behavior of the various samples. Considering the results for the porcine aorta (Fig. 5 and Fig. 6), larger extension ratios are achieved in the uniaxial than the biaxial, as expected, and furthermore the tissue is stiffer and less nonlinear under biaxial loading. The porcine aorta is much less stiff than the human femoral artery, which also displays significant nonlinear elastic behavior to high strains (Fig. 7).

Using the stress-stretch data for both porcine aortic tissue and human femoral arterial tissue, the hyperelastic constants for the Mooney-Rivlin hyperelastic constitutive equation could be established.

The strain-energy function for the nine-parameter model (Eq. (4)₃), was fitted to the uniaxial and biaxial data simultaneously to obtain the hyperelastic constants for this constitutive equation using a nonlinear regression routine. However small changes were found to produce wide variation in the regression parameters when all nine parameters were used, i.e. the results of the nine-parameter fit were not stable, indicating redundant parameters. To overcome this, the hyperelastic constants were determined for a reduced form of the generalized Mooney-Rivlin model, i.e.,

$$W = a_{10}(I_1 - 3) + a_{01}(I_2 - 3) + a_{20}(I_1 - 3)^2 + a_{11}(I_1 - 3)(I_2 - 3) + a_{30}(I_1 - 3)^3 \quad (5)$$

A nonlinear regression routine to determine the parameters of this model is available in MARC (Palo Alto, CA) and that routine was used to determine the five constants of Eq. (5), for porcine aortic tissue and human femoral arterial tissue (Table 1). Note that in the case of a best-fit to the data for the porcine aorta, negative constants result—different constants (resulting in a quite similar stress-stretch curve) result if the parameters are constrained to be non-negative (Table 1). The remaining constants in Eq. (4)₃ were set to zero.

3.2 Analysis of Cardiovascular Stents. The results of the analysis found that the degree of tissue prolapse (i.e., the maximum draping displacement of the tissue) was in increasing order, as follows: the least prolapse was the BeStent 2, next was the TETRA stent, then the NIROYAL, and the highest predicted pro-

lapse was the VELOCITY stent. This order was found for data from both the porcine aorta and the human femoral artery (Fig. 8).

Taking a closer look at the deflections of the tissues within the repeating units, it can be seen that the BeStent 2 has small deflections and maintains a relatively flat surface [Fig. 9(a)] and has two maxima whereas the VELOCITY stent [Fig. 9(b)] and the NIROYAL stent [Fig. 9(c)] have one definite peak of the prolapse. The TETRA stent has a more complex deflection pattern within the repeating unit, with a more extensive 'flat' region [Fig. 9(d)].

The prolapse data can be normalized if a correct inter-comparison of stents is to be achieved because a small repeating-unit will allow little draping but cause problems for the other design objectives for cardiovascular stents listed in the Introduction. In this respect, a repeating-unit is in some way superior if it can minimize prolapse despite having a large area. When the prolapse is normalized for the area of the repeating unit, the TETRA stent and BeStent 2 perform best (Table 2). A similar conclusion is reached if the predicted prolapse is normalized by the length of the periphery of the stent's repeating unit (Table 2).

The stresses provoking intimal hyperplasia and restenosis are suggested to be those in the media layer where damage is caused to the smooth muscle cells [23]. To determine the propensity for restenosis, a measure of the stresses in the media layer directly above the stent are shown in Fig. 10 where it can be seen that the highest stresses are provoked by the VELOCITY stent. It can also be seen that although the TETRA stent has less tissue prolapse than the NIROYAL, more areas of high stress are generated in the media around the TETRA stent. This predicts that a stent may minimize prolapse whilst generating high stresses in the vessel wall at the same time.

4 Discussion

The results of our investigations show that biomechanical differences between stents in clinical use can be ascertained using finite-element modelling and a hyperelastic constitutive model of vascular tissue. To obtain the data necessary to develop the model, we carried out both uniaxial and biaxial tests on human and animal vascular tissues. A system for biaxial testing of small tissue samples was designed and implemented allowing us to develop a constitutive model that could describe the behavior of vascular tissue under both uniaxial and biaxial deformation modes.

The Mooney-Rivlin hyperelastic model was chosen because of the wide availability in commercially available finite element software—in this way, our solution may be readily used by designers of cardiovascular stents to try out new stent geometries virtually before clinical trials. It may also be used to optimize the geometry of stent repeating units. Other constitutive models for vascular tissues have been determined which may indeed be superior to the Mooney-Rivlin model used here, see Fung [24] and Holzapfel et al. [20,25]; however the variability of the elastic behavior observed in tested tissues suggests that the model proposed here is useful for engineering design purposes, especially given the measured variability in the elastic response of aged human tissues (Fig. 7).

For a constitutive model (viz, Eq. (5) and associated constants given in Table 1), the second derivative W with respect to the invariants of B_{ij} must be positive definite [26]; i.e. the slope of the stress-stretch curve must not be less than zero. This imposes the following conditions:

$$\frac{\partial W}{\partial I_1} + (1 + \lambda_1) \frac{\partial W}{\partial I_2} > 0 \quad (6)$$

All sets of constants presented in Table 1 satisfy this condition. The "best-fit" constants for the porcine aortic tissue have a negative a_{10} parameter and therefore do not satisfy the stricter condition that:

$$\frac{\partial W}{\partial I_1} \geq 0, \quad \frac{\partial W}{\partial I_2} \geq 0 \quad (7)$$

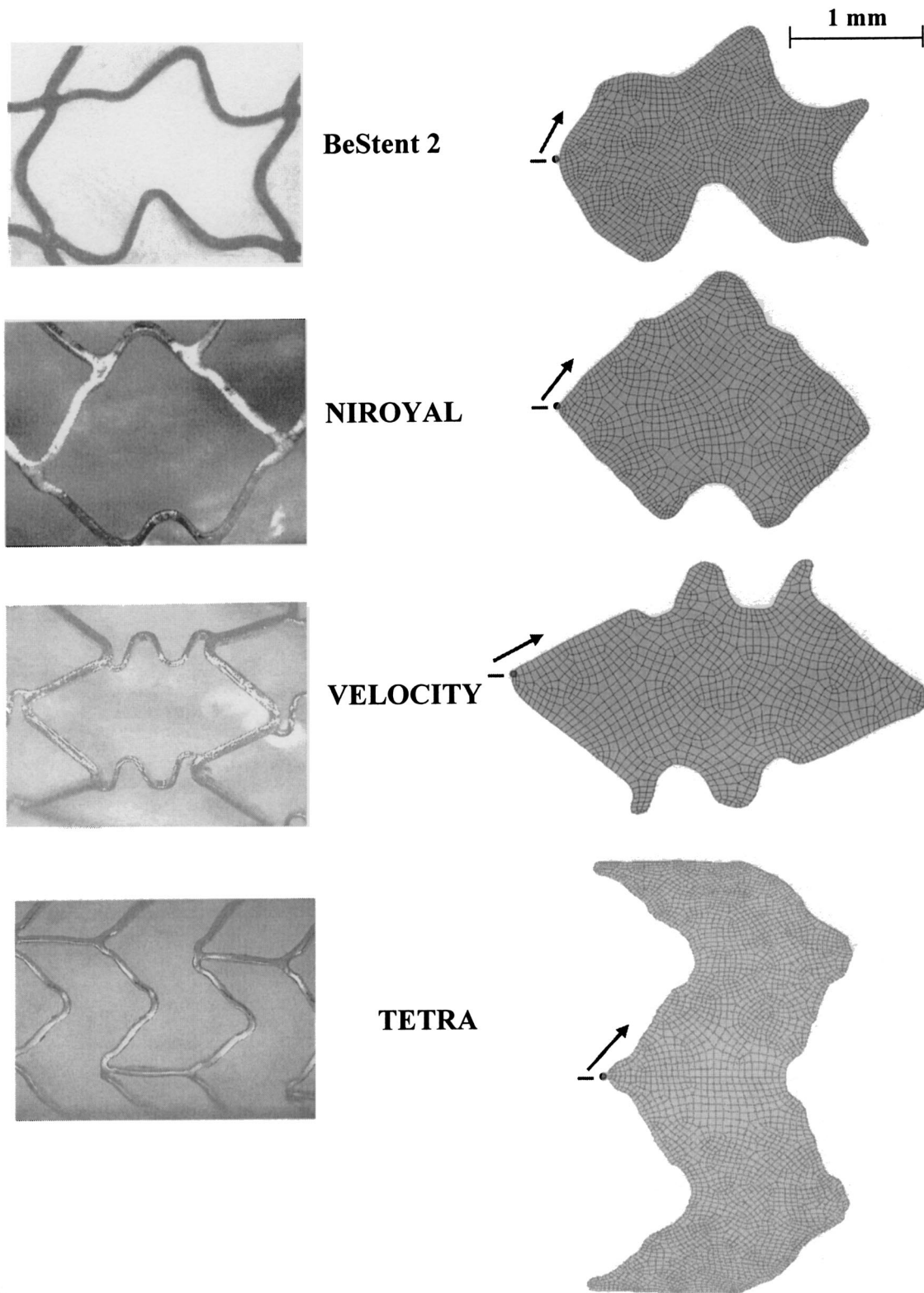


Fig. 4 Four types of stent analyzed in this study; (BeStent 2, Medtronic AVE; NIROYAL, Boston Scientific; VELOCITY, Cordis, and the TETRA Stent, Guidant) and a plan view of finite-element meshes within an *expanded repeating unit*. The arrow indicates the direction and the start point from which the distance around the periphery of the stent is taken.

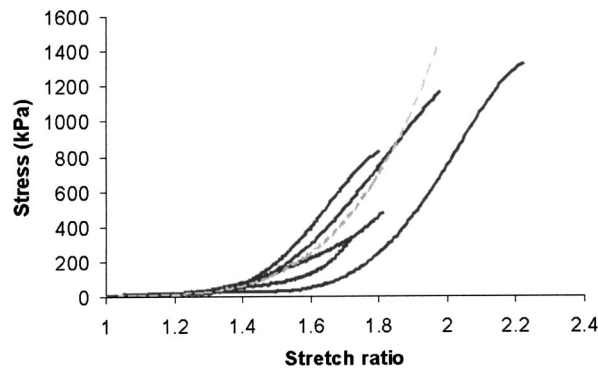


Fig. 5 Five uniaxial stress-stretch curves for pig aorta, with the fitted elastic model (dashed line)

The limitations of this investigation mainly relate to the description of the vessel wall; first the real vessel wall is non-isotropic (different properties in the longitudinal and circumferential directions) and second it is composed of three layers: the intima, media, and adventitia. With regard to the first assumption, for our biaxial data, we took an average value of the stress for

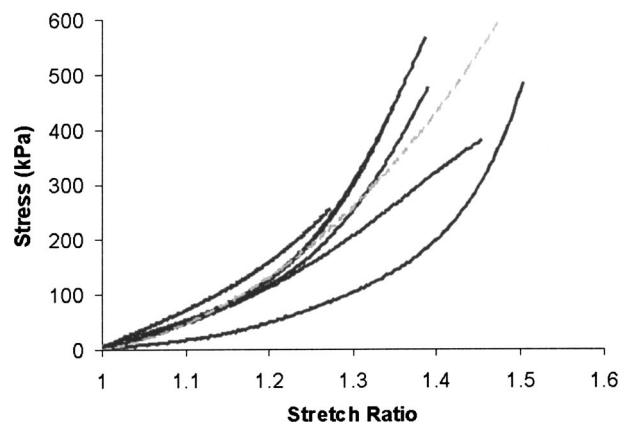


Fig. 6 Five biaxial stress-stretch curves for pig aorta, with the fitted elastic model (dashed line)

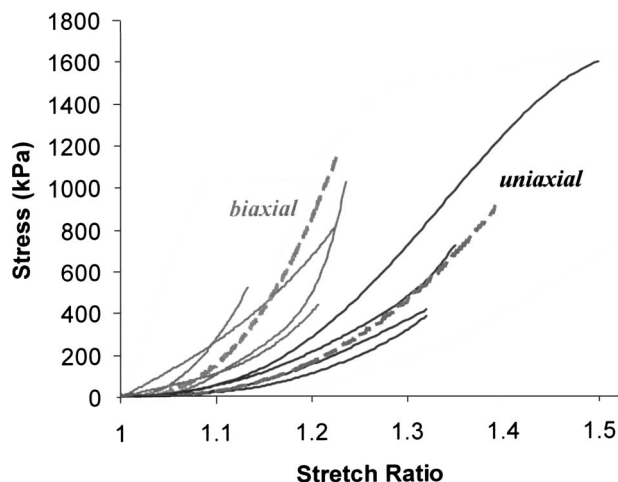


Fig. 7 Uniaxial and biaxial data for the human femoral artery, with the fitted biaxial and uniaxial constitutive models (dashed line)

Table 1 Hyperelastic constants to describe the vascular wall nonlinear elastic behavior. The parameters describe a Mooney-Rivlin model of the form given in Eq. (5).

	Porcine aorta parameters (best-fit values) (kPa)	Porcine aorta parameters (no negative constants) (kPa)	Human femoral artery parameters (best-fit values) (kPa)
a_{10}	-86.35	0	18.90
a_{01}	107.57	15.36	2.75
a_{20}	86.30	0	590.42
a_{11}	-58.87	16.34	857.18
a_{30}	22.97	34.07	0

each value of the stretch allowing us to input a single stress/stretch curve into the nonlinear regression routine. This approach has been used successfully by others [27] and is not expected to make a significant difference to the comparison of stents. Anisotropic constitutive models have been developed for bovine pericardium (e.g. [28]) and blood vessel walls [25,29] but these are not available routinely for design-analysis of the kind pursued in this paper. The second assumption (homogeneity) is mitigated by the fact that the load is mainly borne by the media in an expanded blood vessel. With regard to the testing, it was carried out at room

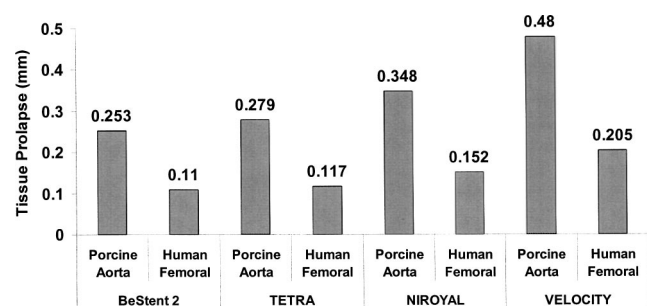


Fig. 8 The maximum prolapse of the vascular tissue within the repeating unit of the stent for each of the four stents analyzed. The result is given for both the porcine aorta properties and the human femoral properties.

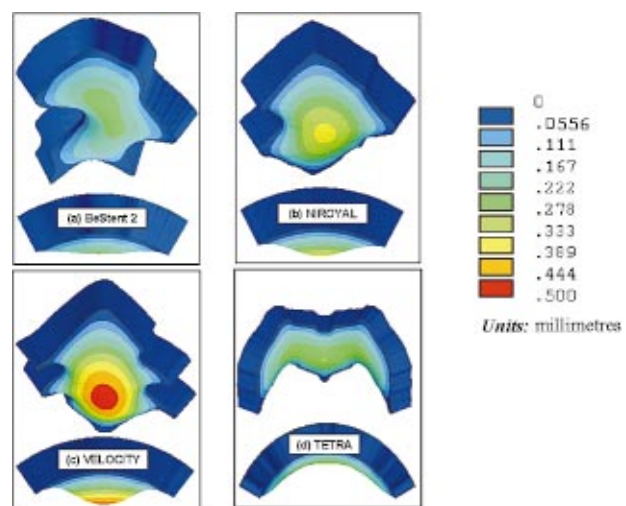
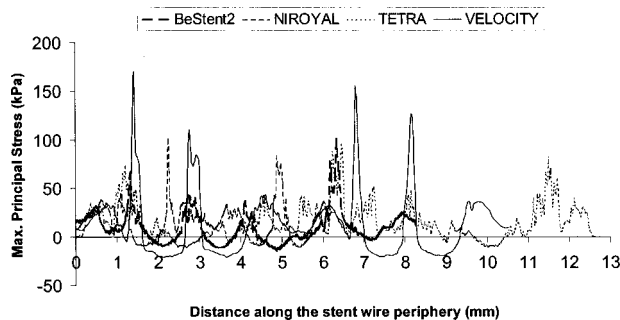


Fig. 9 Prolapse of the four stents: Contour plot of the displacements in the BeStent 2, Medtronic AVE, the NIROYAL, Boston Scientific, the VELOCITY, Cordis; and the Tetra Stent, Guidant

Table 2 Maximum prolapse per unit area of the repeating unit, and per length of the periphery of the repeating unit

Design	Maximum prolapse (mm)	Expanded area of repeating unit (mm ²)	Max. prolapse per unit area (mm/mm ²)	Length of periphery of expanded repeating unit (mm)	Maximum prolapse Per unit length (mm/mm)
BeStent 2	0.253	2.34	1.08×10^{-1}	8.24	0.031
TETRA	0.279	4.35	0.64×10^{-1}	12.60	0.022
NIROYAL	0.348	2.12	1.64×10^{-1}	6.52	0.053
Velocity	0.480	3.71	1.29×10^{-1}	10.5	0.046

**Fig. 10 Maximum principal stress in the mid-layer of the vessel around the periphery of the repeating-unit (i.e., directly above the stent wire). High stresses are indicative of a likelihood of tissue damage and intimal hyperplasia.**

temperature and not body temperature; this is not expected to have a significant effect on tests of only several minutes duration. Finally the range of applicability is limited to the range of the curve fitting on Figs. 5, 6, and 7; however the predicted stretches are all within the testing range.

Other modelling issues relate to the stent/vessel interaction. Firstly, the stent is assumed not to deflect under the compressive force of the vessel wall. We might expect more elastic stents (such as those made of shape memory alloys) to contract, thereby reducing vessel wall stresses. Secondly, longitudinal expansion will be expected to create a shearing motion between the stent and the vessel wall; we have not modelled this—this means that the prolapse relates to what would occur in the final expanded geometry and not what would occur at any step during the stent expansion process. Furthermore, we have not considered the effect of junctions that occur between the repeating-units of some stent designs even though it has been shown, in clinical studies using IVUS, that restenosis is greatest in these regions, e.g. Hoffmann et al. [30] for the central articulation in the Palmaz-Schatz stent. However, none of the four stents analyzed in this study have such articulations.

Comparing the four stents analyzed in this study leads to a conclusion that the BeStent 2 (Medtronic AVE) generates the lowest level of prolapse, and that the VELOCITY stent (Cordis) has the highest level of prolapse. If the analysis is extended to consider the area of the repeating unit—the bigger this is the lower the net damage caused by the stent wires—we are lead to the conclusion that the TETRA stent minimizes the amount of tissue prolapse; however, as Fig. 10 shows, this is achieved at a cost of creating somewhat higher peak stresses in a number of areas in the vessel wall. There may be a detrimental effect of such peak stresses, and further research is needed on this topic. However, it is reasonable to assume that the higher the stress the greater the risk of damage in the media, which is postulated to be the initiating event in the development of smooth muscle cell proliferation and intimal hyperplasia.

It can be seen by comparing Figs. 5 and 6 with Fig. 7 that the aortic tissue is much more elastic than the human femoral tissue in

both uniaxial and biaxial tension. Since the aorta is the most elastic artery in the body [21], it is likely that the diseased coronary artery into which stents are placed will be more similar to human femoral tissue. This is also likely to be true because the human tissue is from elderly individuals of similar age to those undergoing coronary angioplasty. Therefore, the lower values of prolapse for the femoral artery tissue (Fig. 9) is expected to better represent the in vivo case. It should be noted that thickening of the vessel wall due to stenosis itself, which is probably very variable, was not considered in the model; however, this is not expected to affect the qualitative comparison of stents. Nevertheless, an essential future task for studies of this kind will be to develop a hyper-elastic constitutive model for diseased coronary artery tissue.

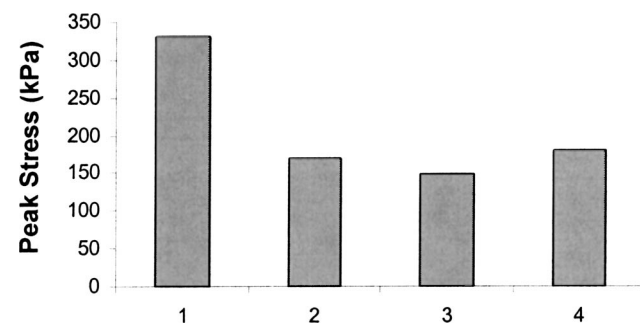
The next step in a biomechanical analysis of stents is to develop a full 3-D model of the stent, in a realistic artery with a stenosis using imaging data of the kind obtained by Messenger et al. [31]. The constitutive model presented in Eq. (5) with the data in Table 1 can be applied directly to 3-D models [32]. Even as drug-eluting or coated stents succeed in reducing re-stenosis rates, the biomechanical nature of the stenting procedure means that the tendency to provoke re-stenosis can only be minimized in absolute terms by designing to account for the biomechanical origin of the disease.

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Appendix

Mesh Convergence Study. Four mesh densities were analyzed for one of the stent designs (the Velocity Stent). The peak stress is determined in each case. It was found that eight elements through the thickness of the vessel was an adequate mesh density (see Fig. 1A). The maximum prolapse did not alter for any of the mesh densities shown.

**Fig. 1A Peak stress vs. mesh type. Mesh type 1: 4 elements through vessel wall; Mesh type 2: 8 elements through vessel wall; Mesh type 3: 12 elements through vessel wall; Mesh type 4: 12 elements through vessel wall, with double the mesh density shown in Fig. 4.**

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